DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Detroit District Office 300 River Place Drive Ste 5900 Detroit, MI 482307 (313) 393-3100	04/13-24-2026 FEI NUMBER 3005949964
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lars Arnoldsen, Corporate VP and General Manager	
FIRM NAME Catalent Indiana LLC	STREET ADDRESS 1300 S Patterson Dr
CITY, STATE, ZIP CODE, COUNTRY Bloomington, IN 47403 USA	TYPE ESTABLISHMENT INSPECTED Sterile 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

Written records of investigations into the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

A. Extrinsic biological particulates (mammalian hair) have continued to be identified in finished sterile drug products. However, investigations into these events have not been completed in a timely manner and do not demonstrate that the root cause has been adequately identified and corrected. From approximately 08/30/2025 to present, you have identified mammalian hair in finished units in at least (b) (4) batches, including three identified in 2026, representing a recurring contamination issue (approximately (b) (4) batches out of (b) (4) inspected in 2026). Probable root cause has been attributed to stopper components; however, this conclusion is based on an ongoing, aggregated trend investigation (REC 1093464), that was opened on 08/28/2025, and has not been substantiated through complete, batch specific investigations. All (b) (4) deviations are currently open. You stated that closure of those deviations is pending completion of this trend investigation. Despite implementation of multiple corrective and preventative actions, you continue to observe mammalian hair in finished drug products.

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B. Investigations into repeated water intrusion events in classified manufacturing areas were not adequate to ensure timely correction of the identified root cause or to evaluate the impact of these events on aseptic operations. On or around 01/05/2026, water intrusion (roof leak) into the aseptic processing area resulted in the cancellation of media fill lot (b) (4) , (b) (4) Line (b) (4)), Room (b) (4), with the root cause attributed to a roof leak and water saturation in the interstitial spaces above manufacturing suites in Building (b) (4)(REC 1149054). On or around 02/15/2026, a second roof leak resulted in water intrusion impacting Vial Line (b) (4)(VL(b) (4) Room (b) (4), and (b) (4), Room (b) (4), during execution of medial fill lot (b) (4) , which was subsequently aborted (REC 1166977). On or around 03/04/2026, a third water intrusion event occurred in Room (b) (4) during execution of media fill lot (b) (4) on VL(b) (4) which was also aborted (REC 1175609). These three events occurred within a period of approximately two months, while corrective actions from the previous deviations remained open and prior to completion of the roof repair.

Despite identification of the roof as the source of the leaks, you did not implement effective interim controls or complete corrective actions prior to resuming manufacturing in the affected areas. Additionally, you did not evaluate the impact of repeated leaks on commercial batches manufactured in the affected areas prior to the repair of the roof in Building (b) (4) on or around 04/14/2026 ((b) (4) batches made on lines VL(b) (4) (b) (4), and Syringe Line(b) (4) (SL(b) (4), and did not implement enhanced environmental monitoring during the period of elevated risk. Review of maintenance records identified multiple prior roof leak events in Building(b) (4) in 2025 (approximately seven work orders), further demonstrating a recurring condition that was not effectively corrected.

C. The defect classification system for visual inspection does not ensure that particulate matter (PM) related defects are consistently evaluated and investigated. For example, you classify PM such as atypical particulates, adhered matter, light/dark particles, and dark/light fibers as intrinsic, unless determined to be extrinsic per A-WI-22-01-002-001, *Work Instruction for Particle and Matter Identification, Evaluation and Trending*, Version: 8, Effective Date: 2026-

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03-30, and do not require an investigation unless the PM is determined to be extrinsic or an action limit is exceeded. As a result, PM identified during visual inspection are not consistently assessed to determine their origin, significance, or potential impact to product quality.

From 07/01/2025 to present, you have identified approximately 84 out of (b) (4) batches with PM during visual inspection, however, only approximately 27 of these occurrences resulted in an investigation.

Additionally, your classification of PM as intrinsic includes materials that are not inherent to the product or process. Review of particle identification data identified multiple instances of various foreign materials including, but not limited to, polyester, fibers, polymers/plastics, which were classified as intrinsic. For example:

- In REC 1100551, opened on 09/15/2025, closed on 10/31/2025, a particle identified as polyester was classified as intrinsic and no corrective actions were implemented. This classification does not establish that the material is inherent to the product.

D. No defined, objective criteria for when to perform additional inspection (ex: a second 100% visual inspection) following identification of critical defects during visual inspection process exists. The procedure, A-SOP-03-04-001, *Performance of AQL for Parenteral Inspections*, Version: 41, Effective Date: 2026-03-09, relies on undefined "factors to consider" rather than establishing clear requirements, and the manual inspection procedure does not address reinspection as part of an investigation. As a result, decisions to perform reinspection are made on a case-by-case basis without documented, risk-based justification, limiting your ability to determine the extent of defects within a batch. For example:

- Deviation REC 1109095, opened on 10/02/2025, closed on 03/31/2026, consisted of a critical extrinsic particle identified during 100% manual visual inspection of lot (b) (4) . However, the investigation did not include reinspection of the batch to assess for

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additional defective units.

- Deviation REC 1129769, opened on 11/18/2025, closed on 04/14/2026, consisted of a defect (product on stopper in the product contact area) that was found during AQL inspection of lot (b) (4) , and the procedure required 100% reinspection to assess for additional defects within the batch. However, you chose not to perform reinspection because the batch was ultimately rejected due to a separate cross-contamination concern. Your investigation acknowledges the potential for additional critical defects in the acceptable population but did not perform reinspection to determine the extent of the condition.

E. You were notified of (b) (4) container/closure integrity testing (CCIT) stability failure on by customer (b) (4) for lot (b) (4) This failure led to subsequent recall (b) (4) opened (b) (4) . You opened complaint 1192226 on 4/15/2026 which failed to include timely and adequate scoping and impact as only approximately (b) (4) lots were assessed which bracketed the subject lot. Your root cause determined inadequate (b) (4) setup resulting in numerous affected sealing stations.

F. You failed to thoroughly investigate the reprocessing of Project Code: (b) (4) , lot (b) (4) , following an out-of-specification (OOS) in-process concentration result. On or around June 25, 2026, a confirmed OOS result of approximately 55.0-55.4 was obtained for the (b) (4) in-process sample (LIR (b) (4)), which exceeds the specification of (b) (4) mg/mL. DEV 1066425, opened on 06/27/2025, closed 08/21/2025, identified the (b) (4) sample result as the likely potential cause of the OOS, however, you also concluded that the cause of the atypical (b) (4) result was unknown and could not be confirmed because no additional (b) (4) sample was retained for testing. The LIR also concluded that not definitive root cause could be determined and that both manufacturing and testing error could not be ruled out, you attributed the event to the (b) (4) result without sufficient evidence to support that determination. This batch was subsequently

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reprocessed through (b) (4) to which an in specification (b) (4) result was met.

G. You observed (b) (4) requalification of bio-decontamination (b) (4) failure for (b) (4) on SL (b) (4) on 8/15/2025 date. While your likely root cause is rouge lot (b) (4) of biological indicators (BIs) your investigation, in part, resulted in repeat testing resulting in 34 (b) (4) BI locations passing. On approximately 10/25/26 you modified your decontamination requalification limits via CC 1110391 along with protocol exception report PER02 initiated 10/02/2026 resulting in passing results while still passing a (b) (4) reduction along. Removed decontamination limits include intra-location failures and an overall BI pass rate of (b) (4). The passing rate of this requalification is approximately (b) (4) % achieved on 10/21/2026.

H. Multiple investigations into deviations and complaints remain open for extended durations (ex: (b) (4)). Approx 147 complaints remain open from 11/25/2025 to present, 368 deviations open since 09/05/2025 to present

I. Customer complaints concerning distributed drug product batches intended to be sterile were not adequately investigated and/or not investigated in a timely manner to determine the root cause and if market action is needed. According to the procedure titled "Customer Complaints" A-SOP-03-01-024, investigations must be completed within the prescribed due date, or an extension request opened. There were 39 complaints opened for damaged, (b) (4) , or (b) (4) that failed to (b) (4) ; 11 of the complaints were closed beyond the extension due date. Additionally, there were 53 complaints for foreign material/matter revealed in sterile drug products; 23 of the complaints were closed beyond the extension due date. The following are some examples:

Complaint (Record)	Date Opened	Due Date	Extended Due Date	Date Closed	Drug Product, Lot	Complaint Summary

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1144293	12/18/2025	01/17/2026	02/17/2026	04/07/2026
1144329	12/18/2025	01/17/2026	03/17/2026	04/02/2026
1144342	12/18/2025	01/17/2026	02/17/2026	04/08/2026
1131010	11/20/2025	12/20/2025	03/20/2026	Open
1133073	11/25/2025	01/15/2026	03/15/2026	Open

(b) (4)

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1135405	12/01/2025	01/28/2026	02/27/2026	Open	(b) (4)

1. Per the procedure titled "Customer Complaints" A-SOP-03-01-024, previous complaints that involve the same drug product lot may require a new investigation if the prior complaint is "not confirmed or confirmed but not CILLC caused, most recent retain inspection passed, and complaint is cross-referenced in the previous investigation."

   There were numerous customer complaints for foreign material/matter in (b) (4)), lot # (b) (4) between 11/2025-03/2026. There were a total of 14 customer complaints of foreign material in the drug product (b) (4)) and eight of those complaints were specific to one lot (i.e., lot # (b) (4)). The firm determined that external factors outside of the firm's control were the root cause of the complaints without thoroughly examining the returned samples and comparing the similarities in the complaints for the same lot of drug product. The firm did not follow procedure A-SOP-03-01-024 and initiate any supplementary investigations to evaluate the potential quality lapse in the purported sterile drug product, due to repeated reported foreign material/matter in the lot.

2. There were approximately 21 customer complaints for the sterile drug product, (b) (4) that involved

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(b) (4) that did not (b) (4) or were damaged between 06/2025-04/13/2026. According to firm management, the finished drug product retains (i.e., complete (b) (4) assembled into (b) (4)) were not inspected during investigations; however, (b) (4) .

Additionally, the procedure titled "Customer Complaints" A-SOP-03-01-024, indicates that retain samples are to be inspected, as applicable to the investigation.

OBSERVATION 2

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

A. Visual inspection methods have been implemented without adequately qualifying inspection sensitivity, defect detectability, or comparability between methods. For example:

Your threshold (b) (4)) studies failed to generate (b) (4) across the full visible range of defects and failed to establish (b) (4) based on defect size at which defects become reliably detectable. Without establishing (b) (4) supported by (b) (4), you have not demonstrated that inspection sensitivity has been adequately qualified or that the visual inspection process is capable of consistently detecting and rejecting critical defects.

Additionally, MVI studies were conducted using aggregated "particulate" defect categories that combined multiple particulate defect types (ex: glass, metal, rubber, fibers). Further, defect units were characterized by using broad size ranges rather than actual measured particle sizes, which

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does not allow for evaluation of detection capability as function of particle size. Review of your threshold studies supporting the manual baseline demonstrated that certain particulate defect types, such as glass, black fiber, and hair, exhibited low or negligible probabilities of detection. However, particulate inspection performance is characterized by using (b) (4) , which masks this variability and does not reflect detection capability for specific defect types or sizes.

B. The visual inspection program is not adequately designed or implemented to ensure that in-process control procedures provide consistent detection, classification, and evaluation of product defects. For example:

Fiber defects (ex: light and dark fibers) identified during visual inspection are classified as Major (b) (4) defects and are described as particulate matter likely originating from the manufacturing process under A-WI-SOP-03-04-001-002, *Parenteral Inspection Defect Criteria List*, Version: 39, Effective Date: 2025-12-17. Your procedures require that particles be identified to determine whether they are intrinsic or extrinsic, however, fiber materials such as polyester fibers and lint from manufacturing materials (such as (b) (4)) are considered intrinsic following identification. As a result, fibers that may originate from the manufacturing environment or personnel are categorized as process related material, rather than extrinsic contamination. This classification does not ensure that fiber particulates are appropriately evaluated withing the context of extrinsic contamination risk.

OBSERVATION 3
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization processes.

Specifically,

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Your sterility assurance program(s) are not adequately established which include airflow studies, intervention analysis to include occluded surfaces and your media fill program.

A. Airflow studies performed on your (b) (4) lines including but not necessarily limited to (b) (4) Line (b) (4)), Syringe Line (b) (SL(b) (4) and Vial Line (b) (4) (VL(b) (4) do not adequately demonstrate the performance of challenging conditions, zones of impact, rejection requirements and adherence to first air principles. Interventions include but are not necessarily limited to the following:

1. High risk interventions change (b) (4)), (b) (4))),(b) (4) b) (4)), (b) (4)

2. Moderate and low risk interventions (b) (4)) (b) (4) (b) (4) or load (b) (4) (b) (4) , (b) (4) (b) (4)) (b) (4) , (b) (4) (b) (4)), (b) (4) (b) (4) (b) (4)

B. Intervention risk assessments and written SOPs do not adequately and comprehensively characterize and document requirements during the performance of interventions:

1. Your intervention risk assessment leverages (b) (4) input parameters as (b) (4) and (b) (4) . In part,(b) (4) lacks adequate assessment as operators are allowed to break first air with their (b) (4) as long as they comply with your written records to include aseptic observer requirements. Interventions impacted include but are not limited to high risk interventions (b) (4) and moderate low risk interventions include (b) (4)

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a. (b) (4) design impacts your risk assessment(s) to specifically include high risk intervention (b) (4)) as this intervention inherently requires first air blockage during its performance. Other interventions lacking adequate space to routinely perform them adequately includes but is not limited to moderate low interventions (b) (4)).

2. Your intervention risk assessment continues to allow for interventions which may include occluded surfaces such as moderate low intervention (b) (4)), as well as atypical interventions.

C. Media fills are not designed to ensure they provide worst case conditions to the aseptic filling process including but not limited to worst case interventions, are not necessarily included. Intervention variation such as line location (to include within and across locations) or zones as well as al (b) (4) used, vial sizes and open vial stress condition(s). Intervention counts performed during approximate period 6/2025 – 12/2025 is included as:

(b) (4)

OBSERVATION 4
The number of containers and amount of material taken from each container is not based upon appropriate criteria.

Specifically,

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Your firm's sampling of incoming stoppers is not based on appropriate statistical criteria and does not ensure that samples are representative of the lot. Specifically, your firm samples (b) (4) of stoppers from each received lot for testing and release, without documented justification that this sampling approach is representative of the entire lot. This practice does not ensure variability within the lot is adequately assessed.

OBSERVATION 5
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

Environmental monitoring is not always performed in response to interventions located and / or impacting critical surfaces. Examples include but are not limited to: (b) (4) , tools to include (b) (4) (b) (4).

OBSERVATION 6
The responsibilities and procedures applicable to the quality unit are not in writing and fully followed.

Specifically,

You lack comprehensive trending analysis regarding your environmental monitoring program as well as your (b) (4) and (b) (4) decontamination (b) (4)) program. Both programs lack adequate spatial analysis such as intra and inter location requirements over justified periods.

OBSERVATION 7
Master production and control records lack complete manufacturing and control instructions.

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Specifically,

The work instruction A-WI-22-06-001-001 titled "Packaging and Labeling Defect Criteria List" that is utilized to assist the Quality Unit in identifying drug product defects during AQL inspections of finished sterile drug product batches is void of detailed critical and major (b) (4) defect descriptions, such as but is not limited to the categories, "(b) (4)" and (b) (4)."

OBSERVATION 8
Equipment used in the manufacture, processing, packing, or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

The (b) (4) Assembly Machine (Equipment ID # (b) (4)) is utilized to assemble and label sterile drug product (b) (4) into (b) (4). The firm assembles and labels the sterile drug products (b) (4) and (b) (4) on the (b) (4) assembly machine.

The equipment performance qualification studies titled "(b) (4) Assembly Machine (System (b) (4)) Performance Qualification Protocol Summary Report-VL-087JUN21, VPQ-(b) (4) 00019-S-VL-087JUN21, Client (b) (4)," effective: 01/23/2023, "(b) (4) Assembly Machine (System (b) (4) Performance Qualification Protocol Summary Report-VL-087JUN21, Client (b) (4) (b) (4) Addendum 11, VPQ(b) (4) -00019-S-VL-087JUN21-ADD11," effective: 01/27/2026, and "(b) (4) Assembly and Labeling Machine (System (b) (4)) Performance Qualification Protocol, A-VPQ-00061-P," effective: 04/08/2025, do not assess the assembly and labeling functionality as indicated in the production of (b) (4) and

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(b) (4)) for the production batch sizes of (b) (4) and (b) (4) finished drug product (b) (4) .

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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."