

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

DISTRICT ADDRESS AND PHONE NUMBER 8050 Marshall Dr., Suite 205 Lenexa, KS 66214 913-495-5100		DATE(S) OF INSPECTION 03/16/2026 to 03/23/2026
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Kristopher J. Preisinger, General Manager		FEI NUMBER 3002929455
FIRM NAME Catalent CTS, LLC	STREET ADDRESS 10245 Hickman Mills Dr	
CITY, STATE, ZIP CODE, COUNTRY Kansas City, MO 64137-1418, USA	TYPE ESTABLISHMENT INSPECTED 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:

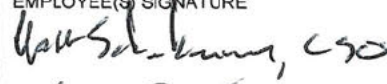
Production and Process Controls

Observation 1

Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, are not established and followed.

Specifically,

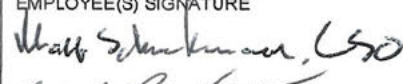
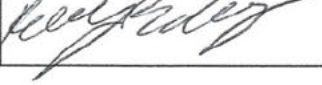
- A) On 03/17/2026 multiple leaks and associated apparent filth were observed at the facility's (b) (4) systems. On this date you manufactured drug products including (b) (4) Capsules Lot (b) (4), (b) (4) Capsules Lots (b) (4), and (b) (4) Capsules Lot (b) (4).
- i) A water leak was observed at the (b) (4) within the (b) (4) system supplying Building (b) (4). Standing water and apparent filth were observed on the floor directly under this leak. Firm personnel stated this leak was known prior to the inspection team's observation, but could neither provide documentation adequately supporting this assertion nor describe the date this leak may have been detected
- ii) Another water leak was observed within the USP (b) (4) system supplying Building (b) (4) at a pipe coupling downstream of the (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Matthew M. Schuckmann, CSO	DATE ISSUED 03/23/2026
		Kelly M. Bromley, CSO	

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8050 Marshall Dr., Suite 205 Lenexa, KS 66214 913-495-5100		03/16/2026 to 03/23/2026	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FEI NUMBER	
Kristopher J. Preisinger, General Manager		3002929455	
FIRM NAME	STREET ADDRESS		
Catalent CTS, LLC	10245 Hickman Mills Dr		
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED		
Kansas City, MO 64137-1418, USA	Drug Manufacturer		

- iii) A third water leak was observed at a (b) (4) tank within the (b) (4) system supplying Building (b) (4). This leak appears to have resulted in standing water and apparent filth on the floor around USP (b) (4) system (b) (4) tanks.
- iv) A water leak was observed at the (b) (4) within the (b) (4) system supplying Building (b) (4).
- B) You failed to follow written procedures for (b) (4) microbial monitoring, which require identifying isolates recovered from the (b) (4) systems to the species level. On or around August 27, 2025, one CFU recovered from the Building (b) (4) USP (b) (4) system (b) (4) was identified to Bacillus group cereus/amyoliquefaciens/atrophaeus. No further speciation was performed to confirm or deny whether this isolate was an objectionable species, and no investigation was initiated.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Matthew M. Schuckmann, CSO	03/23/2026
		Kelly M. Bromley, CSO	

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."