DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	5/18/2026-5/22/2026
	FEI NUMBER 1000110912

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Wallace D. Brisson, Site Head of Operations

FIRM NAME	STREET ADDRESS
Catalent Pharma Solutions LLC	160 S Pharma Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Morrisville, NC 27560-9570	Manufacturer and Contract Testing Lab

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

Specifically,

Your firm has not conducted an adequate evaluation of cleaning and disinfection process subsequent to the completion of Final Report R-539963-R0, Validation of Disinfectants and Sporicides used in the Catalent Pharma Solutions Morrisville Facility, completed on 07/08/2019 by (b) (4). No data has been provided to demonstrate the continued effectiveness of the current disinfectants and sporicides agents against repeatedly recovered environmental microbial isolates at your facility, not previously evaluated in the aforementioned Final Report R-539963-R0. Since 2019, these recovered organisms include *Didymella gardenia, Priestia aryabhattai, Alternaria alternata*, and *Sphingomonas leidyi* which were recovered approximately 47, 77, 24, and 21 instances through (b) (4) environmental monitoring. Moreover, your firm failed to follow PDR-EQO-0034, *Preparation and Proper Use of Approved Cleaners, Disinfectants and Cleaning Materials for Use in the CGMP Production Facility, Version 17.0, Effective Date: May 1, 2024,* in that a disinfectant efficacy study shall be performed every (b) (4), at a minimum.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Harrison E Tandy, Investigator
Ashley N Samuel, Investigator
Tanya R Syffrard, Investigator

X Harrison E Tandy
Investigator
Signed By: HARRISON E. TANDY
Date Signed: 05-22-2026
16:55:38

DATE ISSUED
5/22/2026

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X Ashley N Samuel
Investigator
Signed By: ASHLEY N. SAMUEL -S
Date Signed: 05-22-2026 16:56:40

X Tanya R Syffrard
Investigator
Signed By: TANYA R. SYFFRARD -S
Date Signed: 05-22-2026 16:57:33

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Harrison E Tandy, Investigator
Ashley N Samuel, Investigator
Tanya R Syffrard, Investigator

X Harrison E Tandy
Investigator
Signed By: HARRISON E. TANDY -S
Date Signed: 05-22-2026 16:55:38

DATE ISSUED
5/22/2026

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."