

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

DISTRICT ADDRESS AND PHONE NUMBER 109 Holton Street Winchester, MA 01890 (781) 587-7500 Fax: (781) 587-7556	DATE(S) OF INSPECTION 4/1/2026-4/7/2026* FEI NUMBER 3011696115
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Edward M. Willis, Director, Engineering

FIRM NAME Catalent Massachusetts, LLC	STREET ADDRESS 190 Everett Ave
CITY, STATE, ZIP CODE, COUNTRY Chelsea, MA 02150-1817	TYPE ESTABLISHMENT INSPECTED 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 production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

- A. Your firm failed to follow written procedure, 'BOS-SOP-0249, Aseptic Sampling Technique' which states for (b) (4) samples using (b) (4) the samples are to be taken from sufficient locations to obtain (b) (4). In addition, the procedure states to (b) (4). On 04/02/2026, we observed a Manufacturing Associate, and a Manufacturing Supervisor obtain (b) (4) for (b) (4) Bulk Powder batch # (b) (4). During discussion of the sampling technique, the operators referred to section 8.4 of the procedure on obtaining (b) (4) using (b) (4) however we observed the operator only obtain (b) (4) from the (b) (4), into the IBC (Intermediate Bulk Container). Your firm failed to provide adequate justification for not following your procedure on taking a work-in progress / in-process (b) (4) of (b) (4) Bulk Powder batch # (b) (4) at sufficient locations to obtain (b) (4) of the bulk powder within the IBC.

- B. Your firm failed to follow your written procedure 'SOP-BST-000043, DIA Data Integrity and Security', which states the use of generic accounts is prohibited. During review of previous (b) (4) tests performed on the (b) (4) instrument, Asset ID: Sys-0084, multiple instances of a manufacturing associate performing (b) (4) tests using administrator credentials was observed. This

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Armen H Youssoufian, Investigator Ogechi C Nna, Investigator	Ogechi C Nna Investigator Signed By: 2004009930 Date Signed: 04-07-2026 16:15:32 X	DATE ISSUED 4/7/2026

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includes the following (b) (4) tests recorded on the instrument:

Date	Test Name	Batch	Performed By	Result
(b) (4)			administrator	Passed
			administrator	Failed
			administrator	Passed
			administrator	Passed
			administrator	Passed
			administrator	Passed
			administrator	Passed
			administrator	Passed

The print outs from the (b) (4) tests performed were attached to their associated batch records and initially wet signed by manufacturing associate (b) (6), (b) (7)(C). All manufacturing associates who perform tests on the (b) (4) including manufacturing associate (b) (6), (b) (7)(C) have a unique attributable account to log in with.

***DATES OF INSPECTION**

4/01/2026(Wed), 4/02/2026(Thu), 4/03/2026(Fri), 4/06/2026(Mon), 4/07/2026(Tue)

Armen H Youssoufian
Investigator

X Date Signed: 04-07-2026 16:17:04

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Armen H Youssoufian, Investigator
Ogechi C Nna, Investigator

Ogechi C Nna
Investigator
Signed By: 2004009930
Date Signed: 04-07-2026
16:15:32

X

DATE ISSUED

4/7/2026

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."