DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Ou Ma Telephone: 301-796-8213 Industry Information: www.fda.gov/oc/industry	04/22/2025 - 04/25/2025, 04/28/2025 FEI NUMBER 3015434301

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Scott Gunther, SVP, Quality and Regulatory Affairs

FIRM NAME	STREET ADDRESS
Catalent Maryland, Inc	7555 Harmans Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Harmans, MD 21077	Gene Therapy 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 (I) (WE) OBSERVED:

1. Identity testing is not conducted on the incoming drug substance used in the manufacture of the (b)(4) (b)(4) drug product.

2. Written procedures for sterility release testing of (b)(4) drug product are deficient in that they do not specify a time frame for samples to be tested. Specifically, Document No. 03.0010 Revision No. 10 Effective date 04 Jan 2024 titled Shipment of QC samples does not specify a required time limit from sample collection to performing the tests.

3. Manufacturing equipment is not qualified for its intended use. Specifically, the sterile (b)(4) of the (b)(4) drug product bulk requires monitoring of the (b)(4) as a critical process parameter. The (b)(4) is assessed and documented based on the display shown on the peristaltic pump. However, there is no routine maintenance, calibration or recertification program established for the peristaltic pumps (Equipment ID (b)(4)) used during (b)(4) drug product process performance qualification batches (#s (b)(4)). There is no independent confirmation of the accuracy of this - -.

4. Routine environmental monitoring program is deficient. Specifically, the (b)(4) on the filling system (b)(4) are used in an ambidextrous manner during the filling of the (b)(4) drug product. However, viable surface sampling of (b)(4) is not performed. (b)(4) is monitored according to the Document No. 03.1005 Revision No. 09 Effective date 25 Jul 2024 titled Environmental Monitoring Program-BWI.

5. Procedures for the qualification of personnel for (b)(4) inspection of the drug product vials are inadequate. Specifically,

a. The particulate and (b)(4) are not defined in the defects (b)(4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Ou Ma, Consumer Safety Officer; Alifiya Ghadiali, Lead Consumer Safety Officer; Sarah Underwood, Consumer Safety Officer; Sukyoung Sohn, Biologist	04/28/2025

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b. Not all defects (b)(4) are representative of the vial format for operator training and qualifications Specifically, the fill volumes used during routine (b)(4) inspection is significantly less than the actual product fill volume.

c. The same defects (b)(4) is used for the training as well as the qualification for the (b)(4). Both the 2-mL and the 10-mL defects (b)(4) contain a high percentage of defects ((b)(4), respectively). Too many defects can hinder effective training and qualification of the operators.

d. The defects (b)(4) are visibly marked and do not provide sufficient blinding of the operators during qualification.

6. Written procedures for records retention, archival, and retrieval of controlled documents and records are not followed. Specifically, Document No. 02.0066 Revision No. 02 Effective date 08 May 2023 titled Records Retention, Archival and Retrieval requires that Document Control Archivist maintain a log of (b)(4) (b)(4) including the (b)(4) database. However, on 22 April 2025, the Document Control (b)(4) staff was unable to provide a log of the (b)(4) for the physical executed batch records of the (b)(4) drug product process performance qualification batches (#s (b)(4) and (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 judgement, 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."