DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	1/22/2025-1/30/2025* FEI NUMBER 3013498720

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Suma M. Krishnan, President of Research and Development

FIRM NAME	STREET ADDRESS
Krystal Biotech, Inc.	2100 Wharton St Ste 701
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pittsburgh, PA 15203-1973	Cell & Gene Therapy

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:

1. There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

Approximately 30 deviations were initiated since November 2022 in response to the Beremagene geperpavec (B-VEC) drug substance (b) (4) process (b) (4) of "Concentration (b) (4) " and/or "Concentration (b) (4) " exceeding acceptable ranges per your batch record (b) (4) "KB103 DS Downstream" steps (b) (4) and (b) (4). B-VEC drug substance is manufactured to VYJUVEK drug product at your firm. Your deviation investigations identify inadequate design of your method used to set the acceptable ranges for the (b) (4) acceptable ranges of (b) (4) in (b) (4) Concentration (b) (4) . CAPA-00529 was initiated on 11/20/2023 and closed on 12/19/2024 to address the deviations by (b) (4) the acceptable ranges of the two (b) (4) . Your firm's investigations have not implemented adequate corrective action to mitigate the reoccurrence of the deviations, as the acceptable ranges were not updated in CAPA-00529 for the B-VEC (b) (4) process for further manufacture into VYJUVEK drug product and distribution into the United States market. Since November 2022, your firm has initiated (b) (4) of B-VEC drug substance (b) (4) process and released (b) (4) commercial batches of VYJUVEK drug product into the U.S. market.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Richard L Bartlett, Investigator Lewis K Antwi, Investigator	X Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 01-30-2025 11:59:04	1/30/2025

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The following are examples of the deviations initiated and batches released:

Deviation Number	Drug Substance	Implicated Batch Number	Batch Manufacture Date	Quantity Batch Released to US Market
DEV-00911	Beremagene geperpavec (B-VEC) (b) (4) process	B23096	15AUG2023	(b) (4)
DEV-01012	Beremagene geperpavec (B-VEC) (b) (4) process	B23223	05DEC2023	(b) (4)
DEV-01133	Beremagene geperpavec (B-VEC) (b) (4) process	B24026	30MAR2024	(b) (4)
DEV-01384	Beremagene geperpavec (B-VEC) (b) (4) process	B24181	17SEP2024	(b) (4)

2. Failure to check the reliability of Certificate of Analysis (COA) at Regular Intervals.

Specifically, your firm has not established the reliability of suppliers COA through appropriate validation of the supplier's test result at appropriate intervals for the following components:

Item Code	Material Name

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In addition, you have not established a written procedure describing the sampling and testing of the above materials.

***DATES OF INSPECTION**

1/22/2025(Wed), 1/23/2025(Thu), 1/24/2025(Fri), 1/27/2025(Mon), 1/28/2025(Tue), 1/29/2025(Wed), 1/30/2025(Thu)

X Richard L Bartlett
Investigator
Signed By: Richard L. Bartlett -S
Date Signed: 01-30-2025 11:59:37

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Richard L Bartlett, Investigator Lewis K Antwi, Investigator	X Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 01-30-2025 11:59:04	1/30/2025

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."