DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	8/19/2025-8/27/2025* FEI NUMBER 3012583739

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mitra S. Cruz, Vice President of Manufacturing/Site Head TCF03	
FIRM NAME Kite Pharma, Inc.	STREET ADDRESS 2355 Utah Ave
CITY, STATE, ZIP CODE, COUNTRY El Segundo, CA 90245-4818	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 records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

Corrective actions in response to recurring loss of Quality Control logbook containing GMP data for the following deviations were not effective:

Specifically,

A. Deviation QE-039769 (b) (4), initiated on June 7, 2022 for more than (b) (4) logbooks issued between 2016-2019 were determined to be lost. Missing logbooks were identified from multiple departments, including Quality Control Analytical, Quality Control Microbiology, Quality Assurance, Manufacturing, and Facilities and Engineering.

B. Deviation QE-043118, initiated on October 10, 2022 for missing Quality Control logbook (b) (4) and (b) (4) issued between 2016 and 2019.

C. Deviation QE-007682, initiated March 1, 2023 for missing Quality Control logbooks (b) (4) and (b) (4) issued in 2021.

D. Deviation QE-181486, initiated on December 14, 2023 for missing Quality Control logbook (b) (4) (b) (4) and (b) (4) issued on November, 2022.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Peng Zhou, Investigator Shafiq Ahadi, Investigator	X Peng Zhou Investigator Signed By: 2002104595 Date Signed: 08-27-2025 16:24:27	8/27/2025

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E. Deviation QE-220097, initiated on May 29, 2024 for missing Quality Control logbook (b) (4).

F. Deviation QE-032741 (b) (4), initiated on February 18, 2022 for missing Quality Control logbook (b) (4) issued on July 13, 2016.

In addition, no comprehensive training was provided to address the handling, storage, and archiving of written records.

OBSERVATION 2

Input to and output from the computer, related systems of formulas and records or data are not checked for accuracy.

Specifically, the Electronic Batch Record (EBR), configured on the (b) (4) software, is used to manufacture and release the drug product, Tecartus (brexucabtagene autoleucel). Operational Qualification (OQ) for EBR version 27 was conducted on June 25, 2025, to implement changes under the Master Batch Record Operational Qualification for (b) (4) (b) (4) (Document No. (b) (4)). Your firm did not implement appropriate controls to ensure that changes to the master production and control records do not inadvertently alter the input or operation of currently released version(s) of these records.

For example, your firm implemented two changes—(b) (4) and (b) (4) (b) (4) in the EBR under OQ Document No. (b) (4). However, the OQ failed to verify that the system functions adequately according to its specifications.

OBSERVATION 3

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

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Specifically, process changes for YESCARTA® ® (axicabtagene ciloleucel) to reduce the manufacturing time of a product by (b) (4) were submitted on 29 June 2022. Per the firm's change control record, implementation of (b) (4) Manufacturing process (b) (4) and has potential to reduce turnaround times for manufacturing and improve process robustness. Your firm failed to initiate this process change per the firm's change control procedure as a change record was not initiated until 7 June 2023.

OBSERVATION 4

There is a lack of written procedures describing in sufficient detail the methods, equipment and materials to be used for sanitation.

Specifically, SOP-00194 "Cleaning of the Clean Room", Version 14.0, effective September 15, 2024 requires a solution contact surface time for (b) (4) cleaning for Grade (b) (4) Manufacturing Rooms. However, (b) (4) "Clean Room Cleaning Log" does not require the documentation that disinfectant agent applied for a required contact time on surfaces in Grade (b) (4) Manufacturing Rooms (b) (4). You cannot verify that disinfectants were applied for the required time.

***DATES OF INSPECTION**

8/19/2025(Tue), 8/20/2025(Wed), 8/21/2025(Thu), 8/22/2025(Fri), 8/25/2025(Mon), 8/26/2025(Tue), 8/27/2025(Wed)

X Shafiq Ahadi
Investigator
Signed By: 2000594974
Date Signed: 08-27-2025 16:26:55

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Peng Zhou, Investigator Shafiq Ahadi, Investigator	X Peng Zhou Investigator Signed By: 2002104595 Date Signed: 08-27-2025 16:24:27	8/27/2025

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."