DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	4/3/2025-4/9/2025* FEI NUMBER 1610608

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Danny n.m.i. Cracchiolo, General Manager

FIRM NAME	STREET ADDRESS
Kavis Pharma LLC	12720 Dairy Ashford Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sugar Land, TX 77478-2844	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 OBSERVED:

OBSERVATION 1

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established and written.

Specifically, your firm's procedure, Environmental Air Specifications for Total Particulates, SPC 105, supported by environmental validation report, Environmental Assessment of the Containment Suite I Report Amendment, VA.UTIL.05.REP1, dated 5/13/16, failed to provide adequate scientific rational for environmental sampling frequency and location of areas within your firm's controlled/ non-classified production suites for the monitoring of objectionable microorganisms in drug products not required to be sterile. For example, your firm's document, Environmental Air Specifications for Total Particulates, SPC 105, identifies within Containment Suite (b)(4) Room # 54 Personnel (b)(4) Out, used in the production of (b)(4) non-sterile drug products, defines (b)(4) potential sampling locations with (b)(4) required to be sampled (b)(4) Your firm failed to provide a scientific rational for limiting sampling to (b)(4).

OBSERVATION 2

Backup data is not assured as exact, complete and secure from alteration, erasure or loss through keeping hard copy or alternate systems.

Specifically, your firm failed to back-up your firm's (b)(4) system raw alarm history data documenting the systems operation and functionality to established operating specifications in the production of USP grade (b)(4) used as a component with manufactured non-sterile drug products. Your firm management reported alarm history raw data is saved on the system for

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Camerson E Moore, Investigator X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 04-09-2025 13:57:22	4/9/2025

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approximately (b)(4) days prior to being erased.

OBSERVATION 3

Your firm failed to have systems in place to enable compliance with the verification requirements of the DSCSA.

Specifically, your firm failed to establish a documented process requiring:

A. Notification of FDA and trading partners if suspect product is determined not to be illegitimate.
B. Notification of illegitimate product within (b)(4) hours of a determination of illegitimate product or product with high risk of illegitimacy to FDA and immediate trading partners.
C. Terminating notifications of illegitimate product and notifications of product with high risk of illegitimacy; promptly notifying immediate trading partners of a terminated notification.
D. Employee training regarding your firms DSCSA process for illegitimate product or product with high risk of illegitimacy.

***DATES OF INSPECTION**

4/03/2025(Thu), 4/04/2025(Fri), 4/07/2025(Mon), 4/08/2025(Tue), 4/09/2025(Wed)

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	Camerson E Moore, Investigator X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 04-09-2025 13:57:22	4/9/2025

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."