

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187		DATE(S) OF INSPECTION 6/16/2025-6/20/2025 FEI NUMBER 3018083890	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Janine F Seetahal, Clinical Assistance Professor Rabies Section Head			
FIRM NAME Kansas State Veterinary Diagnostic Laboratory		STREET ADDRESS 2005 Research Park Cir	
CITY, STATE, ZIP CODE, COUNTRY Manhattan, KS 66502-5020		TYPE ESTABLISHMENT INSPECTED Contract Laboratory	
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 Routine calibration of mechanical and electronic equipment is not performed according to a written program designed to assure proper performance. Specifically, this facility performed potency tests and release tests for (b) (4) Drug Product - (b) (4) indicated for p (b) (4) when given (b) (4) or possibly (b) (4) A. Timer, model (b) (4) is used to calculate time between (b) (4) as required per the firm's procedures for (b) (4) Drug Product potency testing. Calibration of the timer, (b) (4), is required (b) (4) and expired as of 13 January 2025. Your firm did not calibrate equipment used to conduct potency testing of a drug product according to the written procedure. B. (b) (4) - Fluorescent Microscope, equipment ID: (b) (4) is used for examination of (b) (4) to determine the number of virus-infected cells per well and create potency test result reports for (b) (4) Drug Product. Calibration of the Fluorescent Microscope, equipment ID: (b) (4) is expired as of 3 June 2025. Your firm did not calibrate the Fluorescent Microscope used to conduct potency testing of a drug product according to the written procedure.			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Shafiq Ahadi, Investigator Shafiq Ahadi Investigator Signed By: 2000594974 Date Signed: 06-20-2025 11:14:57 X _____	
DATE ISSUED 6/20/2025			

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Manhattan, KS 66502-5020

TYPE ESTABLISHMENT INSPECTED

Contract Laboratory

OBSERVATION 2

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, you performed potency tests for (b) (4) Drug Product. A total of (b) (4) lots were tested between (b) (4). Set test records do not include drug product lot numbers tested for potency. A set test record consists of up to (b) (4). For example, your firm tested and released Set # (b) (4) test date (b) (4) for (b) (4) Drug Product (DP). The batch production record does not include drug product lot numbers tested.

OBSERVATION 3

Laboratory records do not include a description of the sample received for testing, the lot number or other distinctive code of the sample and the date the sample was received for testing.

Specifically, your firm performed potency tests for (b) (4) Drug Product. A description of the samples received for testing, including identification, quantity, lot number or other distinctive code, and the date samples were received for testing, is not documented. For example, the standard (b) (4) lot no. (b) (4) used to conduct the potency testing for (b) (4) Drug Product does not have a sample received date or date of testing.

OBSERVATION 4

Written production and process control procedures are not followed in the execution of production and process control functions.

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Shafiq Ahadi, Investigator

Shafiq Ahadi
Investigator
Signed By: 2000594974
Date Signed: 06-20-2025
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Specifically, your firm uses the Rapid Fluorescent Focus Inhibition Test (RFFIT) to determine potency for (b) (4) Drug Product. You did not follow the RFFIT procedure, document no. KSVDL- (b) (4) Version 2, effective date 12/8/2022, to conduct potency and stability testing for (b) (4) Drug Product, Set ID: (b) (4), manufacture date: (b) (4). For example, at the time of drug product testing, calibration of the microscope was expired, and your firm did not verify to ensure the equipment is within calibration before use.

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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 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."