DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/3/2025-12/19/2025* FEI NUMBER 3033262505

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James B. Williams, Owner, Pharmacist

FIRM NAME	STREET ADDRESS
JKR Pharmacy Ventures, LLC dba Doc Lane's Veterinary Pharmacy	101 Venture Ct Ste 125
CITY, STATE, ZIP CODE, COUNTRY Lexington, KY 40511-2645	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Animal Drug Products

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

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A. Your firm is not performing environmental or personnel monitoring in the classified areas (ISO (b)(4)/ISO (b)(4)) each day that sterile drugs products are produced. Viable surface sampling, viable active air sampling, and nonviable air sampling are performed (b) (4) when your rooms and hoods are re-certified. In addition, your firm does not perform non-viable particulate monitoring in the ISO (b)(4) workstations during the production of sterile drug products. Furthermore, the action limit specifications (ISO Class (b) (4) colony forming units per contact plate (cfu/(b)(4) cm2) used for microbiological evaluation of airborne and surface bacteria are not adequate for ISO (b)(4) classified areas, and there is no assurance that the ISO (b)(4) classified areas are tested under dynamic conditions.

B. Your firm is not monitoring each technician working in the ISO (b)(4) Laminar Air Flow Workstations (LAFW) or Biological Safety Cabinet (BSC) Hoods each day drug products are prepared. Your firm is currently sampling the fingertips of technicians only when a media fill is performed. On (b) (4), your pharmacy technicians produced five animal drug products but did not perform fingertip sampling prior to leaving the ISO (b)(4) hoods and buffer rooms after producing the drug

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lisa R Hilliard, Investigator X Lisa R Hilliard Investigator Signed By: Lisa R. Hilliard -S Date Signed: 12-19-2025 11:02:20	12/19/2025

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products, Estradiol Cypionate (ECP) Injection 10 mg/mL (Lot 121025B.37, BUD 01/24/2026), Acetylcysteine Injection Solution (PF) 200 mg/mL (Lot 121025F.57, BUD 01/24/2026), Isoflupredone Acetate Injection Suspension 2 mg/mL (Lot 121025C.29, BUD 01/24/2026), Guanabenz Acetate Injection 20 mg/mL (Lot 120925J.32, BUD 01/23/2026), and Diclofenac Ophthalmic Ointment 0.1% (Lot 121025D.06, BUD 01/24/2026).

C. Your firm is not performing viable active air or nonviable air sampling during media fills.

D. Your firm does not perform gowning qualification, including gown sampling, to ensure pharmacy technicians producing sterile drug products can appropriately don sterile gloves and gowning in ISO (b)(4) areas.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include validation of the aseptic and sterilization process.

Specifically,

A. Media fills or aseptic process simulations performed do not closely simulate actual production conditions or cover worst case conditions. Your firm fails to simulate actual production conditions in every container type during media fills, including vials, droptainers, syringes, and bags. Currently, your technician pharmacists fill media into a total of (b)(4) vials (consisting of (b)(4) vials at (b)(4) and (b)(4) vials at (b)(4) with (b)(4) positive control vials. However, during routine production, your firm fills various size vials ((b)(4) and (b)(4) vials), droptainer bottles ((b)(4), (b)(4)

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(b) (4) syringes, and (b) (4) bags. Additionally, documentation of the media fills performed are incomplete in that they do not include how the media was prepared, and the order in which the vials are filled with media and the volume filled in each, and documentation of all consumables used such as syringes, (b) (4) and vials.

B. Your firm does not perform growth promotion testing on media used during media fills. For example, a media fill was performed on 10/15/2025 using (b) (4) (Lot (b) (4), expiration (b) (4)), but growth promotion testing was not performed or documented for the media lot prior to use.

C. Smoke studies are not performed in any of the four ISO (b) (4) hoods ((b) (4), (b) (4), BSC (b) (4), and BSC (b) (4)) to show that air quality is appropriate to maintain aseptic conditions during the production of sterile drug products. For example, on (b) (4), Isoflupredone Acetate Injection Suspension 2 mg/mL (Lot 121025C.29, BUD 01/24/2026) was produced with a (b) (4), stirrer, beaker, bag of stoppers, (b) (4) tweezers, vials, and (b) (4) foil and (b) (4) bags in the ISO (b) (4) (b) (4) (b) (4) (Workstation (b) (4)). The airflow smoke study pattern tests conducted in October 2025 do not certify that the airflow meets acceptance criteria under these or similar conditions during the production of sterile drug products.

D. Your (b) (4) used to sterilize components and sterile drug products produced onsite, have not been qualified. The effectiveness of the (b) (4) sterilization cycle has not been initially validated or periodically verified. Since 09/03/2025, your firm has dispensed sterile drug product lots that are sterilized via (b) (4) including Diclofenac Ophthalmic Ointment 0.1% (Lot 121025D.06, BUD 01/24/2026) and Estradiol

Cypionate (ECP) Injection 10 mg/mL (Lot 121025B.37, BUD 01/24/2026).

E. You (b) (4) used to sterilize drug products produced onsite, have not been qualified. The effectiveness of the (b) (4) cycle at (b) (4) for (b) (4) minutes, used to render drug product sterile, has not been initially qualified or periodically verified. Since 09/03/2025, your firm has dispensed sterile drug product lots that contain ingredients sterilized via (b) (4), including Diclofenac Ophthalmic Ointment 0.1% (Lot 121025D.06, BUD 01/24/2026) that contains Petrolatum White USP (Lot (b) (4), expiration (b) (4)) and Gentamicin Ophthalmic Ointment 0.3% (Lot, BUD) that contains Petrolatum White USP (Lot (b) (4), expiration (b) (4)).

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

A. Your firm has no written procedure for how to separate multiple batch preparations to prevent contamination or mix-ups during the production of sterile drug products. On (b) (4), (b) (4) preparation of ingredients were performed for (b) (4) drug products, Estradiol Cypionate (ECP) Injection 10 mg/mL (Lot 121025B.37, BUD 01/24/2026), Acetylcysteine Injection Solution (PF) 200 mg/mL (Lot 121025F.57, BUD 01/24/2026), Isoflupredone Acetate Injection Suspension 2 mg/mL (Lot 121025C.29, BUD 01/24/2026), Guanabenz Acetate Injection 20 mg/mL (Lot

120925J.32, BUD 01/23/2026), and Diclofenac Ophthalmic Ointment 0.1% (Lot 121025D.06, BUD 01/24/2026), in the non-hazardous sterile preparation room.

B. Your firm has no written procedure for how to perform (b) (4) testing or (b) (4) testing after the (b) (4) is used to (b) (4) drug product. Your pharmacy technicians performed the (b) (4) testing using a (b) (4) for (b) (4) sterile drug products, including Acetylcysteine Injection Solution (PF) 200 mg/mL (Lot 121025F.57, BUD 01/24/2026), Arginine Injection (L-Arginine) 100 mg/mL (Lot 102025M.57, BUD 12/04/2025), and Guanabenz Acetate Injection 20 mg/mL (Lot 120925J.32, BUD 01/23/2026).

OBSERVATION 4

Clothing of personnel engaged in the manufacturing, processing, packing and holding of drug products is not appropriate for the duties they perform.

Specifically,

Your firm's pharmacy technicians operating in the ISO (b)(4)/ISO (b)(4) classified areas don the following: scrubs worn from home, a disposable non-sterile gown, a single non-sterile hair net, non-sterile face mask, and non-sterile shoe covers. Your firm's general gowning requirements leave exposed skin on the face of personnel including, but not limited their eyes, forehead and neck while preparing sterile drug products in the ISO (b)(4) classified areas.

In addition, when exiting the hazardous sterile preparation room (ISO (b)(4) classified area), the pharmacy technicians and pharmacists completely de-gown of gown, gloves, shoe covers, face mask, and hair net

and then enter the common preparation room (ISO (b) (4) classified area) before exiting the sterile compounding area.

OBSERVATION 5

Written procedures are lacking which describe in sufficient detail the receipt, identification, sampling, testing and approval of components.

Specifically,

A. Your firm does not perform microbiological testing for purchased (b) (4) water used to produce non-sterile drug products. Your firm fails to ensure that the purchased (b) (4) water meets specifications for (b) (4) Water, USP, pharmaceutical use. Non-sterile drug products produced using (b) (4) water include EPM Oral Suspension (Sulfadiazine and Pyrimethamine) 333 mg/ml and 16.67 mg/ml, Penicillin/Gelatin Gutteral Pouch Infusion 250,000 units/mL, Chloramphenicol Ophthalmic Ointment 1%, and Tris EDTA Solution.

B. Your firm uses a store-brand liquid detergent to clean hand wash glassware, utensils and other supplies used to compound non-sterile and non-sterile drug products. Your firm failed to justify the use of a non-pharmaceutical-grade cleaning agent for product-contact equipment and failed to demonstrate that such practices do not adversely affect drug quality.

C. Your firm uses (b) (4) during the production of non-sterile drug products and does not have written procedures that specify the process and criteria for determining and documenting the appropriate hold times or Beyond Use Dates (BUDs) for these (b) (4), such

as Fixed Oil Base, No Flavor Lot (b) (4) (BUD 02/02/2026) used to make Cyproheptadine & Pergolide Suspension (Apple) 200mg/5mL & 1mg/5mL (Lot 110525K.23, BUD 02/02/2026).

OBSERVATION 6

The final and intermediate containers/closures used for drug product intended to be sterile have not been sterilized or depyrogenated.

Specifically,

A. Non-sterile vials and stoppers are purchased and then sterilized and (b) (4) in-house, but the cleaning and sterilization processes for the stoppers and vials have not been validated. Both stoppers and vials are used as the final container for sterile compounded injectable drug products. On 12/10/2025, sterile stoppers and vials were observed being stored in the ISO (b) (4) classified common room and then staged for use for the production of sterile drug products.

In addition, opened but unused rubber stoppers or stoppers not used within (b) (4) days that have already been (b) (4) are allowed to be placed back into inventory and sterilized again. Your firm has not validated the re-sterilization process and has no procedure or process for tracking the number of sterilization cycles for (b) (4) stoppers.

B. Reusable glassware, such as but not limited to beakers, used for weighing and mixing ingredients for drug products are not always sterilized or (b) (4) after cleaning. On 12/10/2025, non-sterile glassware stored on a shelf in the ISO (b) (4) classified common room was staged and then used in sterile compounding preparations.

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OBSERVATION 7

Personnel were observed touching equipment or other surfaces located outside of the ISO (b)(4) area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves.

Specifically, on (b) (4), during the production of Diclofenac Ophthalmic Ointment 0.1% (Lot 121025D.06, BUD 01/24/2026), your firm's sterile compounding technician picked up a balance foot that fell on the floor while wearing sterile gloves. The balance was wiped and the gloves were sprayed with (b) (4). Your pharmacy technician returned to aseptically filling the drug product without changing gloves. The drug product, Diclofenac Ophthalmic Ointment 0.1% (Lot 121025D.06, BUD 01/24/2026), was dispensed as office stock on 12/10/2025.

OBSERVATION 8

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically,

A. Your firm does not conduct routine testing for potency (assay) for all drug products produced by your firm, including both sterile and non-sterile.

B. Your firm does not conduct routine testing of all of your drug products labeled as sterile for sterility and/or endotoxin prior to release and distribution.

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OBSERVATION 9

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, your firm produces sterile and non-sterile drug products using bulk drug substances, excipients, and other materials but does not perform any testing, including an identity test, on the incoming bulk drug substances or excipients used to produce these drug products. Currently, your firm accepts glycerin as an excipient or ingredient for various formulas administered orally without ensuring that the ingredient is tested for Diethylene Glycol (DEG) and Ethylene Glycol (EG) contamination. For example, Omeprazole & Cimetidine Oral Suspension 114 mg/mL & 50 mg/mL (Lot 093025AC.17, BUD 12/29/2025) was produced using Glycerin 99% USP (Lot (b) (4), expiration (b) (4)). Your firm received the certificate of analysis (COA) for glycerin but did not review and document that the supplier tested the lot for DEG/EG and the test results were below acceptable levels for DEG/EG.

OBSERVATION 10

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Your firm does not have a written stability testing program to determine Beyond Use Dates (BUD) placed on all your drug products. Your firm has no written and approved stability protocols and no final written and approved reports. In addition, your firm has not performed container closure integrity testing. For example, the drug product Detomidine HCl & Xylazine Injection 20 mg/ml & 10 mg/ml

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(Lot 112525H.50, BUD 01/09/2026) has an assigned BUD of 45 days. Your firm lacks a written and approved protocol or a scientific rationale to support the assigned BUD.

OBSERVATION 11

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

A. Your firm has no written procedures for the responsibilities of the Quality Unit, including release or rejection of the finished animal drug products.

B. Your firm lacks written procedures for the management and handling of investigation of unexplained discrepancies whether or not the compounded lot has been already distributed and failed to adequately investigate environmental monitoring excursions following the sterile compounding area room recertifications in October 2025. Unacceptable microorganism concentrations were reported for air samples collected from four locations in the common preparation area (ISO [(b)(4)] classification). Total colony forming units (cfu, action level [(b)(4)] cfu) were reported for location C[(b)(4)] (9 cfu), C[(b)(4)] (9 cfu), C[(b)(4)] (13 cfu), and C[(b)(4)] (20 cfu), and the colonies were identified *Bacillus, Micrococcus,* and *Staphylococcus,* non-sporulating fungi, yeasts, and gram-negative rods. No root cause or corrective actions and preventative actions for the excursions were documented. The locations were resampled in December 2025 and unacceptable microorganism concentrations were reported for air samples collected from location C[(b)(4)] (14 cfu) in the sterile area common preparation area. The colonies were identified as gram-negative rods, *Micrococcus*, *Staphylococcus*, and yeasts.

C. Your firm lacks written procedures for the management and handling of current good manufacturing

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practices (CGMP) training, change controls, and adverse events.

D. Written procedures are not review and approved without written or electronic official signatures.

E. Your firm's quality unit do not ensure that batch records do not always include documentation and/or complete documentation for drug products, including the actual production date, date of technician and pharmacist signatures, lot number of the packaging materials such as vials, stoppers, syringes, and bottles used to package finished drug products (sterile and non-sterile), packaging configurations, and identification for equipment such as (b) (4) used for (b) (4) testing.

***DATES OF INSPECTION**

12/03/2025(Wed), 12/04/2025(Thu), 12/05/2025(Fri), 12/08/2025(Mon), 12/09/2025(Tue), 12/10/2025(Wed), 12/11/2025(Thu), 12/15/2025(Mon), 12/16/2025(Tue), 12/17/2025(Wed), 12/18/2025(Thu), 12/19/2025(Fri)

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."