DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	3/9/2026-3/19/2026* FEI NUMBER 3002726048

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Anne M Reese, Pharmacist In Charge

FIRM NAME	STREET ADDRESS
Veterinary Pharmacy Corporation	2008 Sunrise Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Peter, MN 56082-5384	Veterinary Compounding Pharmacy

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

Contamination was observed in your production area and areas adjacent to production areas.

Specifically,

A) A pallet of used compounding equipment was observed in the non-classified Amoxicillin storage room. Items on this pallet included, but were not limited to, used proces (b) (4) which were coated with yellow residue, metal fittings, and hoses. All equipment on this pallet appeared to be coated with a layer of white powder. Your staff stated that this pallet of used equipment had been present in this location for approximately 1.5 to 2 years. This pallet is located immediately adjacent to the door leading to Amoxicillin Room (b) (4) where finished product compounding and packaging of Amoxicillin products takes place.

B) Widespread and extensive damage was observed on the painted drywall walls in the Amoxicillin processing area. This damage included an approximately 6-inch long and 3-inch deep hole punched in a wall from the handle of an over-extended door, multiple scrapes in paint and drywall ranging from 1 to 6 inches, and broken floor ceramic molding. This damage was noted approximately 10 feet from the chute where Amoxicillin capsules were (b) (4) openly into (b) (4) container (b) (4) an (b) (4)

C) Black stains were observed on damaged wall sections where paint and drywall had been scraped off, approximately 10 feet from the chute where Amoxicillin capsules were (b) (4) openly into (b) (4) container (b) (4) an (b) (4) and approximately 10 feet from the capsule grinder/powder sieve, during the grinding operation of Lo (b) (4) of Amoxicillin active ingredient capsules on 3/12/26. This lot was used in the compounding of Ultramox Amoxicillin Lot #VUAN00C1726B on 3/17/26.

D) Dark stains were noted on multiple ceiling vents in Amoxicillin Room (b) (4) above compounding equipment during the production of Ultramox Amoxicillin Lot #VUAN000C0926A on 3/9/26.

E) Personnel were observed moving between the dedicated Amoxicillin compounding area and other locations inside the firm without changes of garbing on 3/9/26 and 3/10/26. Your firm does not have written procedures regarding personnel movement or garbing changes between Amoxicillin and non-Amoxicillin production areas.

F) Your firm does not use a deactivating agent for cleaning Amoxicillin from equipment or packaged finished products exiting the dedicated Amoxicillin compounding area. (b) (4) coated with compounded Amoxicillin powder were observed exiting the dedicated Amoxicillin compounding area carrying packaged finished product to your central warehouse and packaging area on 3/9/26 and 3/10/26 without being cleaned or wiped down with any cleaning agent prior to transport.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nicholas J Presto, Investigator Beatrix D Hippe, Investigator Vaishali J Patel, Investigator	X Nicholas J Presto Investigator Signed By: NICHOLAS J. PRESTO -S Date Signed: 03-19-2026 11:20:32	3/19/2026

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G) Powdered Amoxicillin was observed covering all production equipment in the Amoxicillin Grinding room, Amoxicillin Storage room, and Amoxicillin Room (b) (4) during the production of Ultramox Amoxicillin Lot #VUAN000C0926A on 3/9/26. Piles of powdered excipient used in the compounding of this lot were also noted leaking from a damaged valve onto the floor of Amoxicillin Room (b) (4) at this time.

H) Cobwebs were noted in the overhead scaffolding supporting production equipment in Amoxicillin Room (b) (4) during the production of Ultramox Amoxicillin Lot #VUAN000C0926A on 3/9/26.

I) An approximately 3-foot-long plastic shovel was observed stored laying on the floor of Amoxicillin Room (b) (4) during the production of Ultramox Amoxicillin Lot #VUAN000C0926A on 3/9/26.

J) One pallet containing (b) (4) s of Kolliphol were observed in Compounding Room (b) (4) on 3/10/26 during the compounding of Lot #VIVC126A of Ivermectin. Your staff stated that this Kolliphol was used for R&D use only and was stored in the compounding area because of insufficient storage space in the R&D room.

OBSERVATION 2
Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically,
Aseptic process simulations (media fills), along with the governing procedure SOP CR-02 – Aseptic Technique & Gloved Fingertip / Thumb Test – are deficient in that they do not simulate the finished product container size, number of units, or worst-case conditions that may arise during compounding activities. Media fills conducted by your firm to simulate aseptic processes utilize (b) (4) which contain a total of (b) (4) IV bags and associated equipment. (b) (4) is used by each sterile compounding technician as part of their (b) (4) aseptic process simulation evaluation. During a review of your sterile compounding records for March 2026, a lot size o (b) (4) x 2000 ml bags of Iron 20% (200 mg/ml) was noted in the compounding of Lot #V20030526 on 05MAR2026. This batch was compounded to fulfill Rx (b) (6), (b) (7)(C) and shipped to your customer on 3/11/2026. Additional batch sizes of (b) (4), an (b) (4) x 2000 mL bags were also noted in compounding records from 04MAR2026 – 10MAR2026. Additionally, Form CR-37 – Periodic Cleanroom Aseptic Evaluation – which is used to (b) (4) qualify your sterile technicians, does not document the amount of time required to conduct the media fill using th (b) (4) Start and stop times, along with total operational durations, are also not recorded on your CR-24 – Iron Stock Bag Compounding Forms for compounding activities.

OBSERVATION 3
Deviation from the procedural requirements of a decree of injunction.

Specifically,

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Consent decree number 00-CV-2725 Paragraph 17 requires you to establish, continuously maintain and/or follow procedures, processes and controls to ensure the following: Paragraph 17(A)(vi), Establish and implement Procedures to continually monitor compounded drugs products to ensure that master formula requirements describe in subparagraph 17(A)(vii), are being followed. including but not limited to product strength and absence of pathogens, and, in the case products labeled as sterile; the absence of endotoxins and pyrogens; and Paragraph 17(A)(vii), Ensure that every product that Defendants label as sterile is in fact sterile, and is free of pyrogens and endotoxins.

You manufacture the following sterile products:

Iron 135.33mg/mL, Vitamin B Comp 1.5mg/mL Injectable - 1800ml
Iron 184mg - Gent 8mg - 1500ml
Iron 200mg Injectable
Iron 75mg - Gent 7.5mg - B Comp - 1500mL
Iron 95mg - Gent 5mg - 1500mL
Iron 98.3mg - B Complex - 1500mL
Iron 100 mg/mL Injectable
Iron 133.3 mg - Gent 3.3 mg - Injectable - 1500mL
Iron 100 mg - Gent 3.4 mg - 1500mL Inj
Iron 100 mg - Gent 5 mg INJ -1500mL
Iron 100 - Gent 5 - B-Complex - 1500mL Injection
Iron 100 - Linc 10 - Gent 5 - B-Complex Injection- 1500mL Bag
Iron 173 - Gent 5 - Injection- 1500mL Bag
Iron 173 - Gent 5 - B-Comp - 1500mL Inj
Iron 186.6 - B-Complex INJ - 1500ml Bag
Iron 186.6 - Gent 5 - B-Complex Injection- 1500mL Bag
Iron 180.6 - Linc 24 - B-Comp INJ- 1500mL Bag
Iron 190 - Gent 5 - Injection - 1500mL Bag
Iron 190mg-B-Comp 11.26mg - 2000mL Bag (1800mL Stock Bag)
Iron 50mg/mL, Tylosin 5 mg/mL, B-Complex Injectable
Iron 133.3 mg/mL, Tylosin 8 mg/mL, Gentamicin 3.3 mg/mL Injectable
Iron 150 mg/mL, Tylosin 12.6 mg/mL, Gentamicin 5 mg/mL, B-Complex Injectable
Iron 186.8 mg/mL, Tylosin 12.6 mg/mL Injectable
Iron 100mg/mL, Tylosin 10 mg/mL, B-Complex Injectable - 1500mL
Iron 181.8mg-Gent 4mg-B-Comp 11.5mg - 1500mL Bag (1300mL Stock Bag)
Iron 182.84mg-Gent 8mg-Super B 1.3mg (1300ml Stock Bag)
Iron 75mg-Gent 7.5mg-Super B Comp (1000mL Stock Bag)
Iron 95mg-Gent 5mg Inj (1250ml Stock Bag)
Iron 98.3mg-Super B Injectable (1250ml Stock Bag)
Iron 187.5mg/mL, Tylosin 12.5 mg/mL Injectable - 1600mL

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nicholas J Presto, Investigator Beatrix D Hippe, Investigator Vaishali J Patel, Investigator	X Nicholas J Presto Investigator Signed By: NICHOLAS J. PRESTO -S Date Signed: 03-19-2026 11:20:32	3/19/2026

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CITY, STATE, ZIP CODE, COUNTRY Saint Peter, MN 56082-5384	TYPE ESTABLISHMENT INSPECTED Veterinary Compounding Pharmacy

Iron 180mg-Linc 20mg - 2000mL (1800ml Stock Bag)
Iron 150mg-Linc 15mg-Gent 5mg-Super B Comp (1100ml Stock Bag)
Iron 150mg-Gent 4mg (1100ml Stock Bag)
Iron 150mg-Gent 15mg-Super B Comp (1100ml Stock Bag)
Iron 175mg-Tylosin 12.6mg-Gent 6.1mg (1300ml Stock Bag)

but have not established adequate procedures/processes/controls to ensure each of these products is free of pyrogens and endotoxins in that you do not test each lot of product for pyrogens/ endotoxins. In particular, the following recent sterile compounded lots were released by your firm without endotoxin testing:

V20030426	Iron 20% 2000 ml	04MAR2026
V20030526	Iron 20% 2000 ml	05MAR2026
V20030926	Iron 20% 2000 ml	09MAR2026
V20031026	Iron 20% 2000 ml	10MAR2026
V20031126	Iron 20% 2000 ml	11MAR2026

Additionally, your written procedure, SOP CR-07 – Injectable Product Endotoxin Specifications – is deficient in that it states "A random sample of injectable iron dextran preparation will be sent to a qualified outside laboratory for endotoxin testing (b) (4) ' instead of establishing a procedure for endotoxin testing on every lot of sterile product compounded at your firm.

***DATES OF INSPECTION**
3/09/2026(Mon), 3/10/2026(Tue), 3/11/2026(Wed), 3/12/2026(Thu), 3/13/2026(Fri), 3/16/2026(Mon), 3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu)

X Vaishali J Patel
Investigator
Signed By: 2002647361
Date Signed: 03-19-2026 11:21:04

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EMPLOYEE(S) SIGNATURE
Nicholas J Presto, Investigator
Beatrix D Hippe, Investigator
Vaishali J Patel, Investigator

X Nicholas J Presto
Investigator
Signed By: NICHOLAS J. PRESTO -S
Date Signed: 03-19-2026 11:20:32

DATE ISSUED
3/19/2026

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."