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	8/31/2026-9/10/2026*
	FEI NUMBER 3010485868

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Aaron A. Zamanian, Director of Pharmacy

FIRM NAME	STREET ADDRESS
Victory Medical Center Pharmacy	4303 Victory Dr
CITY, STATE, ZIP CODE, COUNTRY Austin, TX 78704-7507	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile 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

Use of ingredients not intended for pharmaceutical use in sterile drug production.

Specifically, the following was observed, but not limited to:

1) On August 31, 2026, the following dietary supplement grade APIs were observed in your firm's raw material storage area and confirmed to be in use for sterile drug product production:
   - (b) (4) , USP, Lot (b) (4) Expiration Date (b) (4)
   - (b) (4) , Lot (b) (4) , Expiration Date (b) (4)
   - (b) (4) , Lot (b) (4) , Expiration Date (b) (4)

   Each API is labeled as dietary supplement grade.

   On August 31, 2026, your firm was directly observed using the above-referenced dietary supplement grade APIs to aseptically produce ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML) **STOCK SOLUTION**, Lot 2055939, BUD October 20, 2026.

2) On July 16, 2026, your firm used the following dietary supplement grade APIs to aseptically produce B COMPLEX (MDV) DEXPAN/NIACINAMIDE/PYRIDOX HCL/RIBO-5-PHOS/THIAMINE HCL (2/100/2/2/100) **STOCK SOLUTION**, Lot 2018604, BUD December

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13, 2026:

- Pyridoxine HCl, USP (Vitamin B6), dietary supplement grade, Lot (b) (4) , Expiration Date (b) (4)
- Thiamine HCl, USP (Vitamin B1), dietary supplement grade, Lot (b) (4) , Expiration Date (b) (4)
- Magnesium Chloride, USP (Hexahydrate), dietary supplement grade, Lot (b) (4) , Expiration Date (b) (4)

This stock solution was further used as a component in the production of (b) (4) - 50mL vials of ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML) **STOCK SOLUTION**, Lot 2026504, BUD October 15, 2026. (b) (4) - 50mL vials were dispensed on (b) (4)

3) On July 24, 2026, your firm used the following dietary supplement grade API to aseptically produce TIRZEPATIDE/NIACINAMIDE (MDV) 20/2MG/ML **STOCK SOLUTION**, Lot 2024973, BUD October 22, 2026:

- Niacinamide, USP, dietary supplement grade, Lot (b) (4) , Expiration Date (b) (4)

This stock solution was further used to produce (b) (4) — 1 mL syringes of TIRZEPATIDE/NIACINAMIDE (MDV) 20/2MG/ML, Lot 2025318, BUD October 22, 2026. (b) (4) 1mL syringes were subsequently dispensed on (b) (4)

4) On May 29, 2026, your firm used the following dietary supplement grade API to aseptically produce (b) (4) of GLUTATHIONE (MDV) 200MG/ML **STOCK SOLUTION**, Lot 1980219, BUD August 27, 2026.

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- Glutathione ((b)(4)), USP ((b) (4)) (Dietary Supplement Grade), Lot (b) (4) expiration date (b) (4)

This stock solution was further used as a component in the production of the following sterile drug products:

- (b)(4) - 30ml vials of GLUTATHIONE (MDV) 200MG/ML **30ML**, Lot 1981940, BUD August 27, 2026
- (b) (4) 30ml vials of GLUTATHIONE (MDV) 200MG/ML **30ML**, Lot 190571, BUD August 27, 2026
- (b) (4) 30ml vials of GLUTATHIONE (MDV) 200MG/ML **30ML**, Lot 1984345, BUD August 27, 2026

All 3 lots were dispensed. Several confirmed patient illnesses were linked to GLUTATHIONE (MDV) 200MG/ML **STOCK SOLUTION**, Lot 1980219, BUD August 27, 2026 and testing confirmed a positive result for endotoxin in GLUTATHIONE (MDV) 200MG/ML **30ML**, Lot 1984345, BUD August 27, 2026.

OBSERVATION 2
Production areas have difficult to clean or contain porous, particle generating, or visibly dirty equipment or surfaces.

Specifically, on August 31, 2026, the following deficiencies were observed on your firm's (b) (4) ISO 5

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(b) (4) Laminar Airflow Hood:
Caulking material was observed applied along the frame edges of the HEPA filter housing within your firm's (b) (4) ISO 5 (b) (4) Laminar Airflow Hood (LAFH). The caulking exhibited the following defects:

- Uneven and irregular application — The caulking was applied unevenly along the frame seams, resulting in inconsistent thickness and width, with visible ridges, valleys, and surface irregularities. These surface irregularities cannot be adequately cleaned or disinfected and provide sites where microbial contamination, cleaning solution residue, and particulate matter can accumulate and persist despite cleaning efforts.
- Rough and porous surface texture — The caulking surface was visibly rough and non-smooth in texture. A porous, rough surface within an ISO 5 critical zone is inherently incompatible with the cleanliness requirements of a sterile environment, as it cannot be effectively wiped down or disinfected and can harbor microbial contamination within its surface irregularities.
- Discoloration and signs of degradation — The caulking exhibited visible discoloration and signs of aging and chemical degradation, consistent with prolonged exposure to cleaning and disinfecting agents. Degraded caulking material is prone to cracking, flaking, and shedding, generating particles that can directly contaminate the critical production area and the sterile drug products prepared within it.
- Separation and cracking from the frame surface — The caulking appeared to be pulling away from and separating from the frame surface in areas, creating open crevices that cannot be cleaned or disinfected and that serve as harborage points for microbial contamination and a source of particle generation within the ISO 5 environment.
- I observed a (b) (4) located inside your firm's (b) (4) ISO 5 Laminar Airflow Hood (LAFH). The (b) (4) creates gaps along the sides and back of the hood interior. These gaps are not readily accessible for cleaning and disinfection.

Your firm's (b) (4) ISO 5 (b) (4) Laminar Airflow Hood is the only ISO 5 LAFH at the facility, and all sterile drug products are aseptically (b) (4) and filled exclusively within this hood.

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OBSERVATION 3

Personnel were observed manually contacting the inner surface of a sterile container or closure.

Specifically, the following observations were made:

1) During the aseptic production on August 31, 2026 of ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML) **STOCK SOLUTION**, Lot 2055939, BUD October 20, 2026, the following aseptic processing techniques were directly observed:

   - Your firm's sterile technician was observed reaching into a bag of rubber stoppers with a gloved hand to retrieve individual stoppers for placement onto vials. During this retrieval, the sterile technician was observed directly touching the inner surface (product contact area) of the rubber stoppers with their gloved hand.

   - Your firm's sterile technician was observed pouring rubber stoppers directly from the bag onto the surface of the work bench and then using a gloved hand to retrieve individual stoppers from the bench surface for placement onto vials.

2) On September 1, 2026, during the aseptic production of TIRZEPATIDE/L-CARNITINE (25/50MG/ML) **STOCK SOLUTION**, Lot 2057705, BUD November 1, 2026, your firm's sterile technician was observed reaching into a bag containing syringes used for filling with a gloved hand. The syringes were not oriented within the bag in a manner that would prevent direct contact with the product contact surfaces of the syringes during retrieval.

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OBSERVATION 4

The facility design was observed to allow the influx of lesser quality air into a classified area containing higher quality air.

Specifically,

- Your firm's (b) (4) ISO 5 (b) (4) Laminar Airflow Hood (LAFH) is designed in a manner that potentially exposes sterile drug products and sterile containers/closures to air of a lower than ISO 5 classification.

  For example, I observed an air intake vent is located directly behind the sterile technician's working area inside of the ISO 5 LAFH. This vent has not been monitored for unidirectional airflow and is not included in your firm's (b) (4) environmental monitoring sampling program. On August 31, 2026, I observed open and exposed vials of ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML), Lot 2055939, waiting to be stopper, and exposed rubber stoppers directly in front of the air intake vent.

- I observed that your firm's (b) (4) connecting the unclassified space to the ISO 8 buffer room lacks a HEPA filter. This design allows unfiltered, lower-quality air from the unclassified space to enter the ISO 8 ante room.

OBSERVATION 5

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The (b) (4) intended to render final product sterile is not adequate and not appropriate for pharmaceutical use.

Specifically, your firm uses the (b) (4) Ref (b) (4) as its sterilizing (b) (4) for final product (b) (4) . According to the manufacturer's specifications, this (b) (4) has a recommended maximum (b) (4) volume of (b) (4) The following examples demonstrate your firm's failure to adhere to this specification:

- ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML) **STOCK SOLUTION**, Lot 2055939, BUD October 20, 2026 —Your firm's batch record documents the (b) (4) of (b) (4) of solution (b) (4) , with only one (b) (4) documented for (b) (4) testing. (b) (4) a (b) (4) rated for (b) (4) exceeds the manufacturer's recommended (b) (4) volume.

- SEMAGLUTIDE/L-CARNITINE (5/50MG/ML) **STOCK SOLUTION**, Lot 2059406, BUD November 2, 2026 — On September 3, 2026, I observed your firm's personnel using a (b) (4) to aseptically (b) (4) of solution, exceeding the manufacturer's recommended maximum (b) (4) volume of (b) (4) .

- ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML) **STOCK SOLUTION**, Lot 2026504, BUD October 15, 2026 — Your firm's batch record documents the (b) (4) of (b) (4) of solution; however, no sterilizing (b) (4) is documented in the batch record for this lot. When asked, your firm's personnel stated they would have to rely on memory to recall how many (b) (4) were used during (b) (4) of this lot.

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ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML) **STOCK SOLUTION**, Lot 2026504, BUD October 15, 2026, was used to fil(b) (4) - 49ml vials of ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML), Lot 2027642, BUD October 15, 2026. (b) (4) vials were dispensed on (b) (4)

OBSERVATION 6

Failure to conduct post-use (b) (4) testing on (b) (4) used to sterilize drug products.

Specifically, but not limited to, the following examples were observed:

- ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML) **STOCK SOLUTION**, Lot 2026504, BUD October 15, 2026, Qty (b) (4) — No documented (b) (4) test was found in the batch record for this lot.

  ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML) **STOCK SOLUTION**, Lot 2026504, BUD October 15, 2026, was used to fill (b) (4) - 49ml vials of ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML), Lot

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2027642, BUD October 15, 2026 (b) (4) vials were dispensed on (b) (4)

- ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML) **STOCK SOLUTION**, Lot 2055939, BUD October 20, 2026, Qty (b) (4) — Only one (b) (4) test is documented in the batch record; however, your firm's personnel stated that multiple (b) (4) were used during the (b) (4) of this lot. There is no documentation to account for (b) (4) testing of each (b) (4) used. I observed your firm's sterile technician used more than one (b) (4) during production

- SEMAGLUTIDE/L-CARNITINE (2.5/25MG/ML) **STOCK SOLUTION**, Lot 2028524, BUD October 27, 2026, Qty (b) (4) — No documented (b) (4) test was found in the batch record for this lot.

  SEMAGLUTIDE/L-CARNITINE (2.5/25MG/ML) **STOCK SOLUTION**, Lot 2028524, BUD October 27, 2026, was used to fill (b) (4) - 1ml syringes of ELITE SLIM 0.4MG (0.16ML PER SYRINGE), Lot 2030230, BUD October 27, 2026, and (b) (4) - 2ml vials of ELITE SLIM 2.5MG/ML (MDV), Lot 2047285, BUD October 17, 2026 (b) (4) - 1ml syringes were dispensed on (b) (4) .

Your firm's personnel stated that they would have to rely on memory to recall whether a (b) (4) test was performed.

OBSERVATION 7

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Failure to appropriately and regularly clean and disinfect or sterilize equipment located in the ISO 5 area.

Specifically, the following deficiencies were observed:

- The sterile technician failed to clean the sides and back surfaces of the (b) (4) located inside of the ISO 5 LAFH.
- The sterile technician failed to clean in between the grates of the vent located (b) (4) the (b) (4)

These deficiencies were observed on the following occasions:

Between production of TIRZEPATIDE/L-CARNITINE (25/50 MG/ML) STOCK SOLUTION, Lot 2057051, and ZINC SULFATE (MDV) 10 MG/ML STOCK SOLUTION, Lot 2057427, on September 1, 2026; end of day cleaning on September 1, 2026; and end of day cleaning on September 3, 2026.

OBSERVATION 8

Lack of routine environmental monitoring in the ISO 5 area and classified areas.

Specifically, the following deficiencies were observed:

1) Absence of Historical Surface Sampling Data — Your firm was unable to provide surface sampling environmental monitoring data for your ISO 5 Laminar Airflow Hood (LAFH) and classified cleanrooms prior to July 29, 2026.
   Despite this absence of surface sampling data, between June 5, 2026 and July 28, 2026, your firm produced (b) (4) different sterile stock drug solutions intended to be filled into vials or syringes and distributed to patients. For example, on July 27, 2026, your firm produced (b) (4)

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(b) (4) of ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML) **STOCK SOLUTION**, Lot 2026504, BUD October 15, 2026, and filled (b) (4) — 50 mL vials of ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML), Lot 2027642, BUD October 15, 2026. Of those (b) (4) vials, (b) (4) vials were dispensed to patients on (b) (4).

2) Inadequate Surface Sampling of the ISO 5 LAFH — Insufficient Sampling Locations — According to your firm's personnel and the hood recertification records, only one location within the ISO 5 Laminar Airflow Hood is sampled during surface sampling.
3) Failure to Monitor the (b) (4) — Your firm does not perform surface sampling environmental monitoring of the (b) (4) connecting the unclassified laboratory area to the ISO 8 ante room.

OBSERVATION 9

Sterile drugs and Materials were exposed to lower than ISO 5 quality air.

Specifically, sterile wipes used to disinfect your firm's (b) (4) ISO 5 (b) (4) Laminar Airflow Hood (LAFH) were staged open and exposed to lower than ISO 5 quality air prior to use. On August 31, 2026, sterile wipes were observed staged open and exposed on a (b) (4) located in the ISO 7 cleanroom. These wipes were subsequently used to disinfect the firm's (b) (4) ISO 5 (b) (4) (b) (4) LAFH. According to firm personnel, sterile wipes are regularly removed from their packaging and stored open in the ISO 7 cleanroom prior to being used to disinfect the ISO 5 LAFH.

OBSERVATION 10

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

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Specifically, the following deficiencies were observed:

- Media Fill Volume Does Not Represent Worst-Case Production Conditions — According to your firm's media fill records, your firm (b) (4) of solution and fills (b) (4) control vials during media fills. However, your firm's personnel stated that the largest batch size in actual production is (b) (4) syringes. On August 31, 2026, I observed personnel aseptically (b) (4) of ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML), Lot 2056424 and fill (b) (4) - 50ml vials of ELECTRO B COMPLEX (MDV) MAGNESIUM CHLORIDE/CALCIUM CHLORIDE/B COMPLEX/SODIUM BICARBONATE (105MG/28MG/B-COMPLEX,12MG/ML), Lot 2056424 during routine operations.
- Media Fill Container Type Does Not Represent Current Practice — Your firm's media fills are conducted by filling vials only; however, your firm's personnel stated that actual production includes filling syringes, with the largest batch size of (b) (4) syringes.
  On September 1, 2026, I observed your firm's sterile technician fill TIRZEPATIDE/L-CARNITINE (25/50MG/ML), Lot 2057051, BUD November 1, 2026 into (b) (4) - 1mL syringes. According to your firm's personnel, your final containers include 5ml, 30ml, and 50ml vials, and 1ml syringes.
- Initial Media Fills for Personnel Not Performed in Triplicate

OBSERVATION 11

Smoke studies were not performed under dynamic conditions.

Specifically, your firm failed to perform airflow visualization (smoke study) testing under dynamic operating conditions for your (b) (4) ISO 5 (b) (4) Laminar Airflow Hood (LAFH), which is used for the preparation of sterile drug products. No smoke study videos or written protocols exist demonstrating that airflow visualization testing had been performed under dynamic conditions in the ISO 5 LAFH.

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Your recertifying company reported that a smoke study was performed April 14, 2026; however, your firm's personnel stated they had no knowledge of smoke studies ever having been performed in the ISO 5 LAFH.

***DATES OF INSPECTION**

8/31/2026(Mon), 9/01/2026(Tue), 9/02/2026(Wed), 9/03/2026(Thu), 9/04/2026(Fri), 9/08/2026(Tue), 9/09/2026(Wed), 9/10/2026(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Demario L Walls, Investigator X Demario L Walls Investigator Signed By: DEMARIO L. WALLS - S Date Signed: 09-10-2026 15:53:02	9/10/2026

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."