DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/21/2026-5/1/2026* FEI NUMBER 2013342

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David A. Jara Sanhueza, Managing Director

FIRM NAME	STREET ADDRESS
GVS TM, Inc	1630 W Industrial Park St
CITY, STATE, ZIP CODE, COUNTRY Covina, CA 91722-3419	TYPE ESTABLISHMENT INSPECTED Biological Drug 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 WE OBSERVED:

OBSERVATION 1

The quality control unit lacks the responsibility and authority to approve and reject all components, drug product containers, closures, in process materials, packaging material, labeling and drug products.

Specifically, your firm's quality control unit is inadequate and lacks responsibility and authority to approve and reject all aspects of your drug products intended for use in whole blood collection or blood collection via apheresis. For example:

- Employees designated as Quality Unit personnel are also responsible for performing chemistry testing, microbiological testing, and/or participating in production-related activities, which does not allow quality to be independent of production.
- Employees designated as Quality Unit personnel do not have independent authority or responsibility to make final decisions regarding the approval or rejection of components, in-process materials, or finished drug products.

OBSERVATION 2

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, your firm did not conduct a process verification to ensure that the following products were being manufactured in such a way as to ensure their identity, strength, purity, and quality:

AMENDMENT 1

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	Emily B Camire, Investigator Laurissa S Flowers, Investigator Homero W Aguilar, Microbiologist	X Emily B Camire Inves igator Signed By: EMILY B. CAMIRE -S Date Signed: 05-01-2026 09:22:35	5/1/2026

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Covina, CA 91722-3419	Biological Drug Manufacturer

- CP2D 250mL solution, product code 0455A
- AS-3 250mL solution, product code 0460A
- AS-3 300mL solution, product code 0462A
- CP2D/AS-3 Blood collection kits, product code 129-63

These drug products are intended to be used in the collection of whole blood or blood via apheresis.

Since October 2025, your firm has manufactured and distributed approximately

- (b) (4) units of 250mL AS-3 solution, product code 0460A
- (b) (4) units of 250mL CP2D solution, product code 0455A
- (b) (4) units of 300mL AS-3 solution, product code 0462A

OBSERVATION 3

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically, there is a discrepancy between your method validation and your sample preparation testing procedure. Your firm's finished drug product bacterial endotoxin test procedure states that testing is to be performed by (b) (4) samples into a (b) (4). The maximum valid dilution (MVD), that is the highest allowable dilution of a sample that still permits the detection of the regulated endotoxin limit, was calculated to be (b) (4) for your 250mL CP2D solution, product code 0455A. The CP2D solution is tested at a (b) (4) dilution. The MVD was not adjusted proportionally to account for the (b) (4) samples. Furthermore, there was no (b) (4) taken during the endotoxin validation for solutions prepared at GVS TM, Covina. This test is used as a final release criterion for your 250mL CP2D solution, product code 0455A, drug product.

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Since October 2025, your firm has manufactured and distributed approximately (b) (4) units of 250mL CP2D solution, product code 0455A.

OBSERVATION 4

Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of of the drug product.

Specifically, your firm does not calculate the actual and theoretical yields for any steps in your manufacturing of 250mL CP2D solution, part number 0445A, AS-3 250mL solution, part number 0460A and AS-3 300mL solution, part number, 0462A, which are intended to be used in blood collection via apheresis.

OBSERVATION 5

Laboratory records do not include a statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the drug product tested.

Specifically, your firm does not document all invalid test results in your "Finished Product ((b) (4) Test) Log" book. On 04/27/2026, when reviewing the audit trail for the (b) (4) (b) (4), the audit trail documented failed standards on 03/19/2026 and 03/27/2026. Review of the logbook revealed that all invalid assays were not documented for 03/19/2026 or 03/27/2026. The data on the (b) (4) and logbook are used for product endotoxin testing for final batch release.

OBSERVATION 6

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Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, on 04/22/2026, sterility testing of lot (b) (4) was observed. Your firm performs sterility testing on your AS-3 + CP2D blood collection kit, product code 129-63, in the (b) (4) laboratory. The test included only (b) (4) media type, (b) (4) incubation temperature and (b) (4) negative control. The testing doesn't satisfactorily include conditions that can verify finished product is sterile. The sterility test is used for final release of the AS-3 + CP2D blood collection kit, product code 129-63.

OBSERVATION 7

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

Specifically, your firm's environmental monitoring system for your ISO-(b) (4) filling machines is deficient in that it does not accurately measure the environment during filling of your drug product intended for use in blood collection. For example,

1. On April 28, 2026, during the processing of 250mL AS-3 solution, product code 0460A, lot # (b) (4) your microbiologist performed EM according to your firm's (b) (4) EM program ((b) (4) (b) (4)). This program requires specific monitoring activities based on the designated (b) (4). During this observation, passive air sampling plates were placed in the ISO (b) (4) area of the bag filling operation on Line (b) (4), where aseptic processing was occurring. However, active air sampling was performed on Line (b) (4), which was not in use at the time, rather than in the area of active aseptic processing.

OBSERVATION 8

Reprocessing was performed without the review and approval of the quality control unit.

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Specifically, your firm conducts in-process re-working of your drug products without the involvement of the quality control unit, for example:

1. On April 28, 2026, during observation of 250mL AS-3 solution, product code 0460A, lot # (b) (4), processing and filling operations, Quality Control Inspection (QCI) personnel removed two (2) units from the processing line during an in-process quality check for further evaluation.
   a. One (1) unit was observed with a visible (b) (4) on the outer packaging, reportedly attributed to (b) (4) contamination from the packaging line and was discarded.
   b. The second unit was identified with apparent discoloration at the (b) (4) (b) (4). The unit was brought to the production lead for inspection, and it was determined that no discoloration was present after removal from packaging. The unit was then returned to the processing line and allowed to proceed within the lot. Quality was not consulted or involved in the decision to allow the process to be re-worked.

2. On 04/22/2026, we observed CP2D/AS-3 blood collection kits, part number 129-63, lot # (b) (4), post fill and sterilization, being placed into (b) (4) and on 04/24/2026, we observed filling of CP2D/AS-3 blood collection kits. While observing both processes, we noted that in-process reworking occurred. The re-processing was not always documented, and the production lead made the final determination on if it could be re-worked. Quality did not make the decision, and quality was not present on the floor and was not contacted when these observations occurred.

OBSERVATION 9

Written procedures are lacking which describe in sufficient detail the testing of components.

Specifically,

a.) Your firm's growth promotion test is not sufficient in that it does not include a representative (b) (4) for (b) (4). Table 1 of (b) (4) 01-025 "Covina Quality Test Procedure – Growth

AMENDMENT 1

Promotion Test" Revision 0 has the growth promotion requirements for media used during analytical microbiology testing. (b) (4) has a requirement for (b) (4) (b) (4).

b.) Your firm's bioburden test is not sufficient in that it does not include a (b) (4) media or incubation requirement to account for (b) (4). Your firm follows (b) (4) 02-025 "Covina Quality Test Procedure – Microbial Count of Product Mix Blood Bag Products" revision 0 to perform bioburden testing on (b) (4) and (b) (4) (b) (4) blood bag (b) (4). The procedure only includes a requirement for (b) (4), that is (b) (4) incubated at (b) (4).

OBSERVATION 10

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing, processing, packing and holding.

Specifically, on 04/22/2026, we observed CP2D/AS-3 blood collection kits, part number 129-63, lot #(b) (4) post sterilization being placed into (b) (4), on 04/24/2026, we observed filling of CP2D/AS-3 blood collection kits, part number 129-63, lot # (b) (4), and on 04/28/2026 we observed filling of 250mL AS-3 solution, product code 0460A, lot # (b) (4). The following was observed:

1. The cleaning of the filling needles occurred but the batch record does not have a designated area to document the (b) (4) cleaning.
2. Rework occurred for filling and (b) (4), which were not documented in the batch record.
3. The filling batch records do not contain sufficient detail to explain the reason for some discarded

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units.

OBSERVATION 11

Written procedures are not established that describe the in-process controls, tests and examinations to be conducted on appropriate samples of in-process materials of each batch.

Specifically, your firm does not have a procedure describing the rationale for the number of samples to be collected by quality for in-process and final quality inspection testing for your 250mL AS-3 solution, product code 0460A, 300mL AS-3 solution, product code 0462A, 250mL CP2D solution, product code 0455A, and CP2D/AS-3 blood collection kits, part number 129-63 drug products intended for use in whole blood collection or blood collected via apheresis.

OBSERVATION 12

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your firm's quality control unit did not thoroughly review and investigate any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications. For example,

1. Your firm failed to investigate four (4) missing units in Lot #(b) (4). The units were not located. The batch was manufactured on (b) (4) and approved for distribution on (b) (4). Units were distributed between (b) (4).
2. Your firm failed to investigate four (4) missing units in Lot #(b) (4). The units were not located. The batch was manufactured on (b) (4) and approved for distribution on (b) (4). The entire batch was distributed on (b) (4).

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OBSERVATION 13

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

Specifically, we observed multiple instances where employees were not following your firm's standard operating procedures (SOPs) and/or not concurrently documenting their functions. For example:

1. On 04/22/2026, employees were observed placing units into (b) (4) and were not consistently performing the required visual inspection as outlined in (b) (4) -066 Covina Work Instruction – Product Processing in Finishing. Per the SOP, each unit must be (b) (4) inspected (b) (4), and confirmed to be free of defects (b) (4) to packaging. During the observation, multiple packers were seen bypassing these required inspection steps.

OBSERVATION 14

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

Specifically, on 04/28/2026, while observing aseptic filling of AS-3 250mL solution, product code 0460A, lot # (b) (4), on filling line (b) (4), the following was observed:

- HEPA Filters (b) (4) and (b) (4), that are located (b) (4) the fill line had visible (b) (4)
- The wall (b) (4) had visible paint cracking and peeling

Fill line (b) (4) is used to fill CP2D 250mL solution, product code 0455A, AS-3 250mL solution, product code 0460A and AS-3 300mL solution, product code 0462A, which are used in the collection of blood via apheresis.

***DATES OF INSPECTION**

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4/21/2026(Tue), 4/22/2026(Wed), 4/24/2026(Fri), 4/27/2026(Mon), 4/28/2026(Tue), 4/29/2026(Wed), 4/30/2026(Thu), 5/01/2026(Fri)

X Laurissa S Flowers
Investigator
Signed By: LAURISSA S. FLOWERS -S
Date Signed: 05-01-2026 09:23:03

X Homero W Aguilar
Microbiologist
Signed By: Homero W. Aguilar -S
Date Signed: 05-01-2026 09:23:36

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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."