DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	8/17/2026-8/27/2026* FEI NUMBER 3011319445

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ponswamy Rajalingam, President and Owner

FIRM NAME	STREET ADDRESS
Hybrid Pharma LLC	1015 W Newport Center Dr Ste 106a
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Deerfield Beach, FL 33442-7707	Outsourcing Facility

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

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

A. Your (b) (4) (b) (4) laminar flow cabinet serial number (b) (4) used for all your sterile batches has a HEPA filter that provides first air to your ISO-5 filling environment. This HEPA filter at the time of the inspection was observed with stains of unknown origin in the cabinet right side.

This is a repeat observation from the inspection that ended on 11/9/2023.

B. The design of your (b) (4) (b) (4) (b) (4) (b) (4) flow hood cabinet serial number (b) (4) used for all your sterile filled batches, has perforations of approximately the width of one inch throughout the rear-lower side. These perforations do not appear to have strong positive pressure which would prevent air from the ISO 7 to enter the cabinet which could impact the ISO-5 environment and the compounded sterile drug product. These perforations were not assessed during your 2024, 2025, and 2026 airflow studies.

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	Jose R Lopez, Compliance Officer Veronica Fuentes, Investigator Andrew O Ejiofor, Investigator X Veronica Fuentes Investigator Signed By: VERONICA FUENTES -S Date Signed: 08-27-2026 16:35:04	8/27/2026

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C. You failed to clean your ISO 7 buffer room completely after the performing maintenance work in your controlled area before compounding sterile drug product. These were the instances where the room was not cleaned:

1. On 2/27/2026, you paid for the painting of the cleanroom's floor. According to the owner, these paint jobs were on Friday evening, Saturday or Sunday. According to the owner, the floor was prepared by sanding, and then it was painted. After painting, the cleaning maintenance log does not document cleaning of walls and ceiling until 3/21/2026. Between these dates (b) (4) lots were compounded in the ISO 7 cleanroom.

2. On 3/7/2026, you paid for the painting of the Buffer room (b) (4) floor. The floor was prepared by sanding, and then it was painted. After painting, the cleaning maintenance log does not document cleaning of walls and ceiling until 3/21/2026. Between these dates (b) (4) lots were compounded in the ISO 7 cleanroom.

3. The last work performed on the floors was paid on 3/30/2026 for the second coat of the cleanroom. According to the owner, this work was done on the weekend and paid that Monday. The ISO 7 cleanroom walls and ceiling were cleaned on 4/8/2026, 4/13/2026, and 4/17/2026. Between 3/30/2026 and 4/8/2026, (b) (4) batches were compounded in the ISO 7 cleanroom.

The firm did not have a documented change control or CAPA for these floors. The room was certified on 3/20/2026 and not repeated after the conclusion of the floor project.

D. Your firm routinely cleans and disinfects the ISO Class 5 laminar flow cabinet solely using (b) (4) A sporicidal agent is not routinely utilized to sanitize the critical ISO 5 direct

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compounding area. Additionally, a deactivating agent is not used after sterile compounding of hazardous drug, CMP Testosterone Cypionate Injection to prevent cross-contamination.

E. Your ISO 7 cleanroom where your laminar flow hood is located contains (b) (4) HEPA filters that have (b) (4) cleanroom (b) (4) tape attached to the border of these filters. You provided no justification for the reason for using this tape. Additionally, HEPA filters in ISO 7 cleanroom were observed with unsmooth caulking in its corners.

F. The (b) (4) laminar flow cabinet ISO 5 used for all sterile compounded drugs had surfaces that could collect dust and may be difficult to keep clean to include the (b) (4) work bench appeared scratched, had three exposed bolts with oversized (b) (4) retention clip, and an electric outlet cover located approximately two inches above the ISO 5 work surface and directly in the path of where aseptic production occurs. The smoke studies provided are inadequate in assessing the air flow patterns. The placement of the electrical outlet could cause eddies/turbulence that could impact the direct compounding area.

The cabinet was observed with some residue, later confirmed to be leftover glue from a tape in the top, front sash. According to your pharmacy technician, the residue is on the outer side of the cabinet.

This is a repeat observation from the inspection that ended on 11/9/2023.

G. The buffer room (b) (cleanroom) ISO-7 used for all the sterile compounded drugs had surfaces that could collect dust and may be difficult to keep clean including beams with exposed bolts running along the top of the room walls, poles supporting beams in each corner, and protruding metal beams on the ceiling near the HEPA filters, wall baseboard with bolts, and ledges above the windows and doors.

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This is a repeat observation from the inspection that ended on 11/9/2023.

H. The ante room used for gowning and used to enter the ISO-7 buffer rooms had (b) (4) doors which contained (b) (4) at the opened (b) (4) (b) (4) on each (b) (4) doors (b) (4) the ante room leading to the ISO-8 drug preparation room, buffer room (b) (4) and buffer room (b) (4) On 8/17/2026, visible particulates were observed in the (b) (4) (b) (4) of these (b) (4) doors.

This is a repeat observation from the inspection that ended on 11/9/2023.

I. The ISO-8 drug preparation room has base boards that are (b) (4) The ISO-8 painted door frame (towards the anteroom) appeared damaged at the bottom.

This is a repeat observation from the inspection that ended on 11/9/2023.

OBSERVATION 2

Drug product containers and closures were not sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically, your firm reuses sterile vials supplied by an external vendor. The process to clean and (b) (4) these vials is deficient in that:

1. Vials are (b) (4) with (b) (4) and left to dry in the ISO-8 environment. After drying, these (b) (4) vials are stored in an uncontrolled environment, exposing them to unknown bioburden and endotoxin limits prior to (b) (4)

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2. Following the (b) (4), vials are wrapped in (b) (4) and stored in an ISO 8 storage cabinet without an assigned expiration date. These vials can be stored in the ISO 8 cabinet up to (b) (4)

Since these vials are added from different batches, the firm only captures the (b) (4) and not the independent supplier's lot number. When these (b) (4) vials are used, there is no traceability to the original supplier's lot number.

OBSERVATION 3

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

Specifically,

A. The initial media fills simulations conducted by your new Pharmacy Technician (b) (6), (b) (7)(C) between 3/31-6/1/2026 consisted of one configuration or size per media fill simulations. These included (b) (4) units of 1 mL in 3mL syringes, (b) (4) units of 10 mL vials, (b) (4) units of 6 mL vials, (b) (4) units of 30 mL vials, and (b) (4) units of 30 mL vials. Only one media fill was performed for the worst-case condition of (b) (4) solution ((b) (4) units of 30mL vials). This was not a recertification.

This is a repeat observation from the FDA inspection ending on 7/28/2016, 6/24/2019, and 11/9/2023.

B. The LFH smoke flow studies (videos) performed on March 2026 of the (b) (4) (b) (4) (b) (4) laminar flow cabinet serial number (b) (4) did not demonstrate the laminar air flow from the HEPA located above the tray of the open (b) (4) glass vials. Additionally, it did not demonstrate if the electrical outlet cover in the back of the cabinet created turbulence near the direct compounding area. The smoke study did not include all aseptic operations, including interventions. Static conditions were not demonstrated.

Additionally, you do not have a report for this smoke airflow studies. You only have videos for the

smoke simulation.

This is a repeat observation from the FDA inspection ending on 6/24/2019, and 11/9/2023.

C. The acceptance criteria for the post fill surface sampling listed under S*ection Clean Room Testing: Viable and Non-Viable Action Levels and Corrective Action of SOP Environmental Viable Airborne Particle Testing Program, Rev. 3, Effective 10/1/2021* is (b) (4)/contact plate and this is not adequate for monitoring ISO-5 surfaces.

This is a repeat observation from the FDA inspection ending on 11/9/2023.

D. On 8/18/2026, I observed the post fill environmental monitoring performed by your Pharmacy Technician, and the sleeve sample plate contacted the sleeve for less than one (1) second. Your written procedure, Document No. 6.01, Environmental Monitoring During Aseptic Processing, Effective Date: 09/01/2023, does not specify the sampling technique, including duration of contact and/or pressure to ensure gown sleeve samples are collected in a consistent and reproducible manner.

OBSERVATION 4

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

A. Your facility's cleanroom suite is not designed, maintained, or operated to prevent microbiological contamination of your sterile drug products.

1. Your cleanroom suite does not maintain a proper cascading (b) (4) pressure differential. Your ISO 7 Buffer Room (b) (4) is maintained under (b) (4) pressure relative to the adjacent ISO 7 Ante Room. This (b) (4) is documented in your firm's (b) (4) certification reports, including:

* Certification Report, Control ID (b) (4), dated 27 SEP 2025, which documents a pressure of -0.021 inches of water column.
* Certification Report, Control ID (b) (4), dated 20 MAR 2026, which documents a pressure of -0.029 inches of water column.

2. Your firm's electronic pressure monitoring system provided direct evidence that the facility fails to maintain a proper cascading pressure differential between its classified rooms. On August 17, 2026, the monitor displayed the following pressure relationships:
   - ISO 7 Buffer Room (b) (4) +0.03174 in. W.C.
   - ISO 7 Anteroom: +0.07794 in. W.C.
   - ISO 7 Buffer Room (b) (4) +0.00450 in. W.C.

These data demonstrate a (b) (4) pressure cascade where the ISO 7 Anteroom is at a significantly higher pressure than the ISO 7 Buffer Room (b) (4) creating a pathway for lower-quality air to flow into the primary sterile compounding area. Additionally, on 8/18/2026, we observed the container with bulk CMP PROCAINE Hydrochloride (2%) lot 260818A in the ISO 7 area with one of the sides of the container opened to permit the filling tube to exit to (b) (4) and fill vials. This container was in proximity to this exhaust vent.

3. Your HVAC system is not appropriately designed to ensure proper air circulation and removal of contaminants. Specifically:
   i. Your ISO 7 Buffer Room (b) (4) and your ISO 7 Ante Room have no designed mechanical air return vents. The absence of an engineered pathway for air to exit these rooms has resulted in significant over-pressurization, preventing proper top-to-bottom airflow.

   a. To compensate for a lack of mechanical air returns, your firm has (b) (4) and continues to use uncontrolled, (b) (4) "(b) (4) in the solid doors separating classified cleanrooms. This practice destroys the physical barrier of the cleanrooms and prevents the maintenance of a verifiable pressure cascade.

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ii. The air returns for your ISO 7 Buffer Room (b) (in close proximity to ISO 5 (b) (4) and ISO 8 Prep Room consist of open, unsealed cutouts in the walls that vent directly into a non-controlled space and are not equipped with backdraft dampers. Moreover, (b) (4) worktables block the airflow to the vents inside both the ISO 7 Buffer Room (b) and ISO 8 Prep Room. The unclassified side of the ISO 8 Prep Room vent is obstructed by a (b) (4) storage rack containing cluttered materials.

This is a repeat observation from the FDA inspection ending on 7/28/2016 and 11/09/2023.

4. Your firm failed to conduct and document dynamic airflow visualization studies (i.e., smoke studies) in the ISO 7 and ISO 8 classified cleanrooms to demonstrate clean-to-dirty air directionality at critical boundaries, such as doorways and other physical openings between the ISO 7, ISO 8, and unclassified areas.
The firm's ISO 8 preparation has (b) (4), where the firm stores the (b) (4) (b) (4) used for covering containers, vials, trays used for the (b) (4)

B. You completed your ISO 7, ISO 8 and ISO 5 (cabinet) room certification on 3/20/2026. On 3/30/2026, the work for your new floor was completed, after the completion of the cleanroom (Buffer room (b) (4) second coat. After completion of the floor, you failed to repeat the room certification to assess HEPAs, differential pressures, or environmental monitoring. This has not been completed by the time of our inspection.

OBSERVATION 5

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, you failed to complete an adequate investigation or open an investigation for the following discrepancies:

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A. Unexplained discrepancies in laboratory test results are not thoroughly investigated.
Specifically, an unexplained, significant extraneous peak was observed in the Ascorbic Acid HPLC assay for Lot (b) (4) , and there is no record of an investigation into this discrepancy by the quality control unit prior to assigning a passing result.

1. The chromatogram for the analysis of Lot #(b) (4) acquired on 07/28/2026 at 3:26:48 PM, displays a significant, unidentified peak at a retention time of approximately (b) (4) .
2. The corresponding "DEFAULT REPORT" calculates this extraneous peak as representing 0.11% of the total peak area. This peak is entirely absent from the corresponding USP Reference Standard injection.
3. Despite the presence of this unknown peak, the "Ascorbic acid assay HPLC" summary report documents the result for Lot #(b) (4) as "Pass" with no documented investigation, impurity evaluation, or assessment regarding the nature of the contaminant.

B. You did not have a completed cleaning maintenance log of the Buffer (b)(ISO 7 (where the LFH ISO 5 is located) for the month of August. You completed a logbook that contains check marks, comment, and initials, but this log page contains no month. It is unknown if this log is for the month of August. By 8/24/26, you had not opened an investigation for this discrepancy.

C. You completed (b) (4) cleaning maintenance logs for ISO 8 Preparation room. It is unknown if cleaning was performed (b) (4) , or if the information was copied. By 8/24/26, you had not opened an investigation for this discrepancy.

D. On 8/19/2026, during the post fill of CMP Buprenorphine HCl (PF) lot 260819A, your Pharmacy Technician sampled (b) (4) environmental monitoring plates, (b) (4) of these were labeled the same, (b) (4) (as in (b) (4) (b) (4) There was a sample location missing, which was the surface flow hood sample since it appears there was a mistake that was made during the labeling. Your Pharmacy Technician said that he knows which one is the surface flow hood and which one was the correct (b) (4) (b) (4) Upon discovery, the

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Quality Assurance director instructed him to write the explanation on the sheet of paper with the plates. By 8/24/26, you had not opened an investigation for this discrepancy.

E. You failed to adequately investigate a "burst" in the tube while (b) (4) Sodium Chloride into Ascorbic Acid for lots 250605A and 250605B. This was captured in an incident report and a blank sheet of paper which was only included in Ascorbic Acid lot 250605B batch report. The investigation does not reference how much was (b) (4) when the burst happened, and if the replacement (b) (4) was the same as the original (b) (4) (since an additional lot was not added to the batch record). You used the maintenance of the (b) (4) of this batch as the basis for the product quality determination without adequate justification.

Additionally, Ascorbic Acid lot 240605A had 11 vials with defects detected in the visual inspection from a total of (b) (4) vials (b) (4) 5.88%). According to your written procedure, *Module 8-68.2 QC-01, Visual Inspection, Revision 1, "based upon the yield up to* (b) (4) *of a batch can be rejected for cracks, defects, particulates, or precipitates before an entire batch is rejected"*. However, this batch was not rejected or the 5.88% of defects were not investigated.

F. You failed to investigate entries for your July 2026 Log Sheet for Temperature Records in Pharmacy, Refrigerator and Freezer, multiple entries were concealed with white-out, and the original data recorded under these entries are unknown.

OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

2. You do not routinely test your Ascorbic Acid for Injection, 500 mg/mL, for the "Limit of Oxalate", a known compendial impurity, and have not scientifically established the omission of this impurity testing.

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1. From January 2024 to May 2026, you released over (b) (4) batches (approximately over (b) (4) vials) of Ascorbic Acid for Injection without performing routine release testing for oxalate. While you performed a qualitative limit test on (b) (4) selected batches on a (b) (4) (b) (4) as documented in "Absence of oxalate-Ascorbic acid injection" (dated October 30, 2023), you failed to test the other batches released over this two-year period.

2. Your firm did not use a compendial reference standard for assay testing. The non-compendial standard your firm used has not been characterized and qualified as a reference standard. As documented in "Ascorbic acid Assay Method Validation", dated 8/29/2021, your method validation for Ascorbic Acid used a standard purchased from (b) (4) (lot (b) (4)) which was not a USP reference standard.

This is a repeat observation from the inspection ending on 11/9/2023.

B. You failed to properly incubate settle plates during your (b) (4) environmental monitoring performed in June 2026. Your settle plates were incubated at (b) (4) from (b) (4) , and at (b) (4) from (b) (4) . The incubation period at (b) (4) should have been for (b) (4) however, the plates were incubated for only 4 days.

C. You failed to properly incubate environmental monitoring plates taken during the production of sterile drug product, Ascorbic Acid lot 260602A. Your settle plates were incubated at (b) (4) from (b) (4) , and at (b) (4) from (b) (4) (b) (4) . The incubation period at (b) (4) should have been for (b) (4) however, the plates were incubated for only 4 days.

D. During your (b) (4) environmental monitoring performed June 2026, you documented your verification and review (b) (4) of the (b) (4) incubation of

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(b) (4) on (b) (4) The (b) (4) incubation (b) (4) from (b) (4) was not performed or documented. It is unknown if the settle plates were read after the (b) (4) incubation.

E. You "calibrate" your scales used to measure materials for the compounding of sterile and non-sterile drug product in house. This is done (b) (4) using your certified weights from (b) (4) to (b) (4). These certified weights have not been re-certified since they were acquired. Additionally, the check weigh is not verified (b) (4) the scales are (b) (4)

OBSERVATION 7

Aseptic processing areas are deficient in that floors are not smooth and/or hard surfaces that are easily cleanable.

Specifically, the ISO-7 buffer room (b) has cracks on the new (b) (4) floor which was completed between February and March 2026. These cracks were observed in the floor adjacent where the laminar flow hood ISO-5 is kept, and close to door towards the anteroom ISO-7. These cracks are not easily cleanable.

Additionally, peeling of this new (b) (4) floor was observed in the anteroom ISO-7 exposing the old (b) (4) floor beneath.

This is a repeat observation from the inspections that ended on 6/24/2019, and 11/9/2023.

OBSERVATION 8

There is no quality control unit.

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Specifically, your firm has a lack of Quality oversight. The lack of Quality oversight was observed in the following:

A. Quality does not issue the batch record to be compounded. Batch records can be printed by any personnel.

B. You do not perform acceptance quality limit (AQL) sampling and visual inspection on finished injectable drug product batches following 100% manual visual inspection, to verify the effectiveness of the 100% visual inspection process and ensure units are free of visible particulate matter and container-closure defects prior to release and distribution.

C. The HPLC data acquisition software (b) (4) lacks security controls to prevent the deletion of system and error logs. On 8/24/2026, facility personnel inadvertently deleted system error logs within the software while attempting to export electronic data files during the inspection.

Additionally, the software was configured without access restrictions, administrative privileges, or an audit trail to record the deletion, user ID, and timestamp of erased logs. Your firm lacks written procedures for data export, routine audit trail review, and archival controls for the (b) (4) system to prevent loss of critical system event records.

D. Logbooks are in loose sheets of paper. There are no bounded notebooks for equipment logbook (except (b) (4)), temperature and humidity logbooks, cleaning logbook and laboratory notebooks. There are no controls for these log pages, as there could be two of the same log pages at a time. These log pages are not issued by quality.

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E. There is a lack of control in analytical sheets. Analytical sheets are not numbers and are not provided by Quality.

F. Quality failed to approve several written procedures. Some of the written procedures that were observed without approval included but was not limited to:

1. Document No. 6.01, Environmental Monitoring During Aseptic Processing, Effective Date: 09/01/2023.
2. SOP No. 3.017 – Safe Handling of Hazardous Drugs
3. SOP No. 200 – Policy and Procedures for USP 800 Hazardous Drugs
4. SOP No. 3.028 – Storage and Transport of Hazardous Drugs
5. SOP No. 3.030 – Hazardous Drug Spill Kit
6. SOP No. 3.032 – Disposing of Cytotoxic or Hazardous Drug Waste
7. Doc No. Module 6-EM-65A, Surface sampling in all ISO classified areas, Rev 2.
8. Doc No. Module 6-EM-64B, Environmental Viable Airborne Particle Testing Program, Rev 3.
9. Doc No. Module 6-EM-60, Clean Room Suite Environmental Monitoring (EM), Rev 3.

G. Quality Unit does not perform oversight of Personnel Monitoring post-fill. Personnel perform self-sampling and self-label the plates after sampling.

H. Quality Unit does not perform Environmental Monitoring on compounding days in the ISO 8 preparation room. This is not done for active air, nonviable particles, and surface sampling.

I. Quality Unit does not approve the results of Environmental Monitoring as observed in the following:

1. (b) (4) Environmental Monitoring performed in June 2026.
2. (b) (4) Environmental Monitoring that was performed in July 2026.

J. Your Quality Assurance (b) (6), (b) (7)(C) performed the in-house calibration and approved it. Calibrations

must be performed by one person and approved by quality.

K. You have not completed Annual Product Reviews (APR) since an unknown date. During our inspection, no APRs were provided.

OBSERVATION 9

Your firm failed to establish adequate 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,

A. Your non-viable (b) (4) Particle Counter Asset ID: (b) (4) used in your ISO-5 Laminar Flow Cabinet is calibrated every (b) (4) This equipment was last calibrated on May, 22, 2026 and the time recorded in the print-out of this equipment is incorrect by (b) (4) and (b) (4) . The equipment calibration is due on (b) (4) Calibration of every (b) (4) is not adequately justified for particle counters in ISO-5 as it may give a false negative result of the ISO-5 environment.

B. Your non-viable (b) (4) Particle Counter Asset ID:(b) (4) used in you ISO-7 Buffer room (b) (4) where your laminar flow cabinet is located, is calibrated every (b) (4) This equipment was last calibrated on October 21, 2024, and it is due on (b) (4) Calibration of every (b) (4) is not adequately justified for particle counters in ISO-7 as it may give a false negative result of the ISO-7 environment.

C. You calibrate your ISO-7 Buffer room (b) ((ID# (b) (4) and Anteroom (ID# (b) (4) (b) (4) (b) (4) in house. You place all devices at the same location along with a standard (NIST) device at the same temperature (C/F) and humidity (%) for about (b) (4) . Your acceptance criteria are temperature within (b) (4) and humidity (b) (4) meet the specifications. You do not perform multi-point calibration with different environments, including low point (operational

minimum), midpoint, and highpoint (operational maximum) temperature and humidity. This calibration is not acceptable since you cannot prove linearity, and there is no evidence the temperature and humidity sensors can drift evenly if the temperature is different from the temperature calibrated at.

D. You failed to keep the (b) (4) ID# (b) (4) in a location to assess the correct temperature of the area where the compounded sterile product is dispensed. This (b) (4) is kept in (b) (4) of the table in ISO-7 Buffer room (b) (4) The sterile product is filled at approximately more than six feet where the (b) (4) is kept at. The temperature and humidity could be different closer to the laminar flow cabinet due to additional generation of heat. On 8/18/2026, during our observation of dispensed batch CMP PROCAINE Hydrochloride (2%) lot 260818A, the temperature was recorded at 71.2˚F and humidity of 55.1%.

E. You failed to document your change and/or verification of the (b) (4) of the (b) (4) containment receptacle in ISO-8 preparation room. According to your Quality Assurance (b) (6), (b) (7)(C), the (b) (4) is verified and/or changed every (b) (4), and they know it must be changed when the transparent (b) (4) (b) (4) can be seen with (b) (4) This (b) (4) containment (b) (4) is used to (b) (4) of (b) (4) when it is weighed in the (b) (4) containment hood. The lack of documentation for this (b) (4) containment receptacle creates the concern that there could be a possible backflow and/or not appropriate (b) (4).

F. You failed to perform an adequate hold time study for your (b) (4) of glass vials used as primary containers for finished drug product. This study does not contain raw data, sample size, (b) (4) lot numbers, (b) (4) date and (b) (4), when it was tested, report number or approvals.

OBSERVATION 10

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	8/17/2026-8/27/2026* FEI NUMBER 3011319445

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ponswamy Rajalingam, President and Owner	
FIRM NAME Hybrid Pharma LLC	STREET ADDRESS 1015 W Newport Center Dr Ste 106a
CITY, STATE, ZIP CODE, COUNTRY Deerfield Beach, FL 33442-7707	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Specifically,

The firm uses a (b) (4) for the compounding of both hazardous and non-hazardous drug substances. Progesterone (classified as a Group 2 hazardous drug) and Testosterone (classified as a Group 3 hazardous drug) were stated to be handled in the same (b) (4) hood as non-hazardous drug substances, as confirmed by the firm's own Pharmacy Hazardous Drug List, which identifies progesterone (b) (4) (b) (4) testosterone cypionate (b) (4) and testosterone USP (b) (4) among the hazardous compounding (b) (4) handled at the facility.

A review of the following firm's written procedures and documents provided to investigators revealed no written procedures addressing the shared use of the (b) (4) hood between hazardous and non-hazardous drug products:

- **SOP No. 3.017 – Safe Handling of Hazardous Drugs*:** This SOP does not establish any cleaning or decontamination requirements specific to transitioning between hazardous and non-hazardous drug operations in a shared hood. No procedures were identified requiring verification of the absence of hazardous drug residue prior to non-hazardous drug compounding in the same equipment.
- **SOP – Handling Hazardous Drugs, Effective Date: 8/25/2023:** This SOP does not mention the scenario in which the same (b) (4) is used for non-hazardous drug compounding. No procedures were identified that: (1) differentiate cleaning or decontamination requirements when transitioning between hazardous and non-hazardous drug operations; or (2) require analytical or visual testing to confirm the absence of hazardous drug residue or carryover prior to non-hazardous drug compounding.
- **SOP No. 200 – Policy and Procedures for USP 800 Hazardous Drugs*:** This SOP does not address shared hood use between hazardous and non-hazardous drug products, nor does it establish any residue monitoring or carryover verification requirements.
- **SOP No. 3.028 – Storage and Transport of Hazardous Drugs*:** Addresses storage and transport of hazardous drugs only. No procedures relevant to shared hood use, equipment

cleaning between drug categories, or carryover prevention were identified in this SOP.

- **SOP No. 3.030 – Hazardous Drug Spill Kit*:** Addresses spill response procedures and spill kit contents only. No procedures relevant to shared hood use or cleaning between hazardous and non-hazardous operations were identified in this SOP.
- **SOP No. 3.032 – Disposing of Cytotoxic or Hazardous Drug Waste*:** Addresses disposal of cytotoxic and hazardous drug waste only. No procedures relevant to shared hood use, equipment cleaning between drug categories, or carryover prevention were identified in this SOP.
  (*None of these SOPs have effective date or revision number)

No residue monitoring program, carryover verification protocol, or cleaning validation specific to the shared use of the (b) (4) hood between hazardous and non-hazardous drug products was identified in any SOP or document provided to investigators. The absence of adequate written procedures and controls for the shared (b) (4) hood presents a risk that non-hazardous drug products may be contaminated with hazardous drug residues, which could have a harmful effect on product quality and patient safety.

Additionally, **SOP – Handling Hazardous Drugs, Effective Date: 8/25/2023,** under the cleaning section, requires the use of (b) (4) RTU. On 8/17/2026, during our interview with your Pharmacist Intern, she explained that she only uses (b) (4) . On 8/19/2026, the Pharmacist Intern explained that the Quality Assurance (b) (5), (b) (7)(C)) explained to her that she was performing the cleaning of the non-sterile hood at (b) (4) with (b) (4) RTU, but she was unaware of this. However, this cleaning performed by Quality Assurance (b) (5), (b) (7)(C) is not documented in the Form 78NS-Cleaning Maintenance Log: Prescription room/ Non-sterile compounding room (Rev 1) log from January-August 2026.

This is a repeat observation from FDA inspection ending on 11/9/2023.

OBSERVATION 11

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Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

A. The scale used during compounding operations generates printouts that do not capture the date and time of the weighing activity. The absence of date and time information on scale printouts limits the ability to establish traceability of weighing data to specific batch production events and undermines the completeness of batch production records.

This is a repeat observation from FDA inspection ending on 11/9/2023.

B. The ISO-8 drug preparation room had a tile and grout floor located under the firm's (b) (4) containment hood that houses (b) (4) scales that are used for weighing non-sterile drug substances, excipients, and (b) (4) . This tile and grout floor could be a surface that if contaminated by various bulk drug substance would be hard to clean and may be a resource for facility wide cross contamination through employee movement and cleaning implements such as mops.

Additionally, on 8/17/2026, we observed a wooden paint brush in this (b) (4) containment hood. This wooden paint brush was used to dust off residual (b) (4) from scales in this hood. The (b) (4) which is porous, and fibers of the brush make it difficult to clean and dry and could be a potential source of cross contamination.

This is a repeat observation from FDA inspection ending on 11/9/2023.

OBSERVATION 12

Employees engaged in the manufacture, processing, packing and holding of a drug product lack the education, training and experience required to perform their assigned functions.

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Specifically,

A. On 8/18/2026, your Pharmacy Technician (b) (6), (b) (7)(C)) was observed performing manufacturing operations, specifically weighing and mixing, during compounding activities. During the observation, the Quality Control (b) (6), (b) (7)(C) provided direct, ongoing supervision and instruction throughout the operations. The level of direction and guidance provided raised concerns as to whether the personnel can independently perform this critical compounding operation in accordance with established procedures.

B. On 8/18/2026, the licensed pharmacist was present at the facility, however, direct supervision of compounding operation was performed by your Quality Control (b) (6), (b) (7)(C) who does not hold the requisite. It was confirmed and verified during the inspection that she is not a registered pharmacist. The supervision of compounding operations by an individual who does not hold the requisite professional licensure and qualifications raises significant concerns regarding the adequacy of oversight of drug manufacturing activities at this facility. Personnel responsible for supervising manufacturing operations must possess the education, training, experience, and where applicable, professional licensure necessary to ensure that compounding operations are performed in accordance with CGMP requirements and applicable regulations.

Additionally, supervision of the sterile dispensing operations held in the ISO-5 is performed from the ISO-8 environment (by viewing the process from a (b) (4) On 8/18/2026, during the filling of CMP PROCAINE Hydrochloride (2%) lot 260818A, supervision of sterile filling operations was conducted from outside the ISO-7 cleanroom environment, through a (b) (4) into the ISO-5 area (inside Buffer room (b) (4) This did not provide adequate oversight to ensure that aseptic techniques were being followed, as the supervisor was unable to verify if first are was being blocked during the filling of vials, if environmental monitoring was being conducted appropriately, or if environmental monitoring samples were being labeled correctly.

OBSERVATION 13

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jose R Lopez, Compliance Officer Veronica Fuentes, Investigator Andrew O Ejiofor, Investigator	X Veronica Fuentes Investigator Signed By: VERONICA FUENTES Date Signed: 08-27-2026 16:35:04	8/27/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet each appropriate specification as a condition for their approval and release.

Specifically, you have not established written procedures defining the testing requirements for drug products placed in quarantine due to a temperature out-of-specification (OOS) condition. As a result, there is no assurance that affected drug products are adequately tested to confirm they meet established specifications for identity, strength, quality, and purity prior to release or disposition.

Firm personnel were asked to describe the testing procedure for product quarantined following a temperature OOS event. The personnel were unable to provide the procedure and deferred to the Quality Control (b) (6), (b) (7)(C) She stated verbally that potency testing is performed on quarantined product; however, this practice was not documented in any written procedure reviewed.

Additionally, no written procedures were identified addressing: (1) whether microbiological testing is required for quarantined product; (2) the testing and disposition requirements for finished product that had already been released and distributed prior to identification of the temperature excursion; and (3) the acceptance criteria applied to any testing performed on quarantined product prior to a release or rejection.

OBSERVATION 14

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented.

Specifically, your test method validations for drug products are inadequate in that they fail to demonstrate the methods are stability-indicating, specific, accurate, and reproducible for their intended use.

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	Jose R Lopez, Compliance Officer Veronica Fuentes, Investigator Andrew O Ejiofor, Investigator X Veronica Fuentes Investigator Signed By: VERONICA FUENTES -S Date Signed: 08-27-2026 16:35:04	8/27/2026

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A. Your test method validation for the (b) (4) used to determine the assay/potency of Ascorbic Acid for Injection, 500 mg/mL, did not demonstrate the specificity of the test method for the finished drug product.

i. Your validation study, documented in "Validation studies - Hybrid Ascorbic Acid 500 mg-ml Validation Studies" (executed for batch TR210829, dated 08/29/2021), concludes that (b) (4) (b) (4) did not interfere with the (b) (4) reaction. You have not performed testing to show the (b) (4) method can distinguish the active ingredient from known impurities or degradation products.

☐ Your internal study, titled "Absence of oxalate-Ascorbic acid injection" (dated October 30, 2023), shows lack of specificity of the (b) (4) test method. In an attempt to prove (b) (4) (b) (4) did not interfere, the study concludes that (b) (4) (b) (4) of a (b) (4) (b) (4) did not alter the (b) (4) result (remaining at (b) (4) confirming the method does not detect this known degradant/impurity.

ii. Your validation for accuracy and repeatability in "Validation studies - Hybrid Ascorbic Acid 500 mg-ml Validation Studies" (executed for batch TR210829, dated 08/29/2021) was inadequate. You tested only one concentration of Ascorbic Acid (b) (4) times and failed to generate statistical data across multiple varying concentration levels. Therefore, you have no documented assurance that your method can accurately detect sub-potent or super-potent batches outside of that single tested target.

B. Your in-house Ascorbic Acid injection HPLC method, as outlined in "Test Method for Ascorbic Acid for injection HPLC test method and testing forms", has not been adequately validated for its intended use.

i. No documentation was provided to demonstrate that a forced degradation study was conducted

to evaluate whether impurities and/or degradants interfere with the analysis. Therefore, the method has not been demonstrated to be stability-indicating.

C. Your firm's practice of utilizing a non-specific (b) (4) (b) (4) method as the primary mechanism for batch release, supplemented only by the (b) (4) or (b) (4) application of an unvalidated in-house HPLC method, is scientifically unjustified and fails to resolve established laboratory control deficiencies. Neither analytical method has been subjected to adequate validation to demonstrate accuracy, precision, and specificity for the finished dosage form. The intermittent use of a secondary, unvalidated method does not compensate for the inherent lack of specificity in your primary release assay, nor does it provide the necessary scientific assurance that all distributed batches conform to safety and purity standards.

i. Your firm uses a non-specific, unvalidated test ((b) (4) for routine batch release, and only triggers the HPLC method reactively if the (b) (4) result falls outside an "action limit" ((b) (4) (b) (4)

This is a repeated observation from FDA inspections ending on 7/28/2016, 6/20/2019, 9/3/2021, and 11/09/2023.

D. Your firm's test methods for sterility are not established and documented to ensure they are accurate and sensitive. Specifically, your procedure "Sterility Method Suitability" fails to conform to the requirements of USP <71> for demonstrating method suitability (bacteriostasis and fungistasis). The procedure does not include the challenge organism Clostridium sporogenes, an anaerobic bacterium required by the USP. The procedure lacks a defined, scientifically sound, and validated method for neutralizing antimicrobial properties of drug products. It vaguely states to "Modify the conditions" without specifying how these modifications should be developed and validated.

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OBSERVATION 15

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

Specifically, your facility's (b) (4) cleanroom certification reports are deficient and fail to demonstrate a state of control.

A) Your firm failed to perform concurrent viable environmental monitoring (microbial air and surface sampling) during the (b) (4) cleanroom physical certifications. This data is absent from your certification reports dated (b) (4) 2025 (Control ID: (b) (4) and (b) (4) 2026 (Control ID:(b) (4)).

B) Your firm failed to establish formal specifications for critical cleanroom parameters. In the Certification Report dated 27 SEP 2025 (Control ID: (b) (4)), key performance data, including HEPA filter airflow velocities and Air Changes per Hour (ACPH) for the ISO 8 Prep Room, are marked as "For Reference Only" and are not formally passed or failed against established criteria.

C) The documentation for HEPA filter integrity testing is inadequate. Your certification reports provide only a summary "Pass" status and lack detailed, filter-by-filter raw data, such as aerosol challenge concentrations and individual leak percentages.

This is a repeat observation from the FDA inspections ending on 06/20/2019, 09/03/2021, and 11/09/2023.

OBSERVATION 16

Your outsourcing facility compounds drug products using bulk drug substances that cannot be used in compounding under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because they (a) are not used to compound drug products that appear on the drug shortage list in effect under

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	Jose R Lopez, Compliance Officer Veronica Fuentes, Investigator Andrew O Ejiofor, Investigator X Veronica Fuentes Investigator Signed By: VERONICA FUENTES Date Signed: 08-27-2026 16:35:04	8/27/2026

section 506E of the Act and (b) do not appear on a list developed by FDA of bulk drug substances for which there is a clinical need.

Specifically, your facility compounded human drug products using semaglutide and tirzepatide bulk drug substances.

OBSERVATION 17

Laboratory records do not include complete records of the periodic calibration of laboratory instruments.

Specifically, the documentation and chromatographic raw data provided for the "Calibration and Performance Maintenance of HPLC, (b) (4) " are incomplete, contradictory, and fail to demonstrate that the instrument is operating in a verified state of control as detailed below:

A. The firm maintains multiple, conflicting records for the same performance qualification event. For example, one "Reproducibility Test" report sheet documents an (b) (4) -injection sequence with a calculated %RSD of 0.15%. This sheet is unsigned and undated, referencing raw chromatograms acquired on 09/19/2025. A separate, conflicting "Reproducibility Test" report sheet documents a (b) (4) -injection sequence with a calculated %RSD of 0.2142%. This sheet is also unsigned and undated, referencing raw chromatograms acquired on 09/19/2025.

B. Test records, such as the "Flow Rate Accuracy Test" report sheet, remain completely unexecuted and undated. For example, the fields for "WEIGHT OF SAMPLE, g" contain only placeholder values (b) (4) for the solvent sample weights, leaving the flow rate accuracy of the pump completely unverified.

C. Chromatogram raw data acquired on 09/19/2025 (and printed on 01/25/2026) was generated using a (b) (4) "(b) (4) Standard" (Lot #(b) (4)) that had expired prior to use. According to the accompanying handwritten, undated "Test Materials and Test Equipment Certification" form, this standard carried an expiration date of October 31, 2023. Consequently, the reference

standard used to qualify the system was expired by nearly two years at the time of testing.

D. A review of the raw chromatogram printouts from the 09/19/2025 sequence reveals active system suitability and contamination issues that were neither investigated nor resolved:

1. The chromatogram designated as a "blank/solvent" injection (found within Result File: blank001.rst) shows significant baseline noise and a distinct, unexpected peak at approximately 0.310 minutes, indicating carryover from previous runs or contamination of the mobile phase/autosampler system.
2. Chromatograms representing test injections (found under Result File: rsd-001.rst) display noticeable peak tailing for the main (b) (4) peak (Retention Time ~0.206 minutes) and erratic baseline drift, indicating potential column degradation or detector lamp instability.

E. Records for executed tests fail to document the calibration status of the measuring equipment used to qualify the HPLC system:

1. The "Oven Temperature Accuracy" report sheet (referencing recorded test measurements of (b) (4) has no entry in the "Next Calibration Date" field for the "(b) (4) (b) (4) or (b) (4) " used to verify the column oven.
2. The "Test Report" sheet for the certification of test equipment fails to document the "Last Cal. Date" and "Next Cal. Due" columns for the (b) (4) balance (Serial Number: (b) (4)) used for gravimetric verification.

F. There is a total absence of Quality Unit oversight and analyst verification across all calibration record packages,. Specifically, the executed test reports or summary sheets, including the handwritten, undated "Performance Certification of an HPLC Autosampler" form and the corresponding printed test summaries, did not contain the required signatures or dates in the "Qualifying Engineer" or "Reviewed By" signature fields. This complete lack of documented review and authorization leaves the operational suitability and calibration status of the system

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Ponswamy Rajalingam, President and Owner

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completely unverified by the quality unit.

***DATES OF INSPECTION**

8/17/2026(Mon), 8/18/2026(Tue), 8/19/2026(Wed), 8/20/2026(Thu), 8/21/2026(Fri), 8/24/2026(Mon), 8/26/2026(Wed), 8/27/2026(Thu)

X Andrew O Ejiofor
Investigator
Signed By: ANDREW O. EJIOFOR -S
Date Signed: 08-27-2026 16:35:30

X Jose R Lopez
Compliance Officer
Signed By: JOSE R. LOPEZ MARTINEZ -S
Date Signed: 08-27-2026 16:36:23

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EMPLOYEE(S) SIGNATURE

Jose R Lopez, Compliance Officer
Veronica Fuentes, Investigator
Andrew O Ejiofor, Investigator

X Veronica Fuentes
Investigator
Signed By: VERONICA FUENTES -S
Date Signed: 08-27-2026 16:35:04

DATE ISSUED
8/27/2026

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."