

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768		DATE(S) OF INSPECTION 8/20/2026-9/3/2026* FEI NUMBER 3009724085			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Michael A. Bogard, Director of Pharmacy					
FIRM NAME OPS International Inc dba Olympia Pharmaceuticals		STREET ADDRESS 6700 Conroy Rd Ste 155			
CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515		TYPE ESTABLISHMENT INSPECTED 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 monitoring environmental conditions. Specifically, (A) The firm's environmental monitoring procedure does not require viable environmental monitoring during the initial aseptic setup of the (b) (4) filling line within the (b) (4) _____ or during the initial aseptic setup of the (b) (4) automated filling machine positioned under (b) (4) _____; HEPA-filtered unidirectional airflow enclosure. Per SOP-009, <i>Environmental Monitoring of the Controlled Production Areas</i>, environmental monitoring is not required to commence until aseptic connections setup activities have occurred. (1) On August 26, 2026, we observed operator (b) (6), (b) (7)(C) performing set-up of the (b) (4) _____ for the (b) (4) automated filling machine (Equipment ID # (b) (4)) for the filling of Calcium Chloride (Lot #H24A01-26). No environmental monitoring plates were present within the ISO 5 critical area under the (b) (4) unidirectional airflow unit during this setup activity. (2) According to the batch record for Myer's Cocktail (Lot # G27A05-26, Exp. 26 Nov 2026), equipment set-up of the (b) (4) auto filler, located inside the ISO (b) (4) in Suite (b) (4) began at 08:01. The first passive air sample was not opened until 08:21 on 30 July 2026. (B) The firm's personnel monitoring program does not include microbiological monitoring of gown locations for Sterile Techs who perform set-up of the (b) (4) filling line or set-up of the (b) (4) automated filling machine. Gown monitoring at a defined schedule, supported by scientific justification, is not included in the program. (1) On August 21, 2026, we observed Sterile Tech (b) (6), (b) (7)(C) performing line setup for the filling of Biotin 0.5 mg/mL (Lot # H17A05-26) with his head, body, and sleeves inside the ISO 5 (b) (4) chamber					
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- without any concurrent personnel monitoring.
- (2) On August 26, 2026, we observed Sterile Tech (b) (6), (b) (7)(C) performing set up for the filling of Calcium Chloride (Lot #H24A01-26) with his sleeves inside the ISO 5 (b) (4), HEPA-filtered unidirectional airflow enclosure (LAFW-(b) (4)). The automated (b) (4) filling machine (b) (4) operates under (b) (4), HEPA-filtered unidirectional airflow enclosure with no physical barrier between the filling operation and the operator.
- (C) Gloved fingertip monitoring of the Sterile Tech is performed only following completion of the aseptic filling production shift.

OBSERVATION 2

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

Specifically,

- (A) Your firm has not adequately demonstrated that (b) (4) -sterilized machine (b) (4) parts and accessories used in aseptic filling maintain their sterile state during the established (b) (4) post-sterilization hold time in a controlled, non-classified area. The supporting microbiological evaluation consisted of swabbing part surfaces and incubating samples in (b) (4) medium at (b) (4) for (b) (4).
- (1) Your firm has not provided adequate scientific justification that these incubation conditions are suitable for recovering and detecting microorganisms that may be encountered if the sterile barrier is compromised during storage within the non-classified area.
- (2) The provided recorded associated with the sampling, in-house incubation, and results of the swab samples lacked the following critical information:
- ☐ Actual incubation temperature
 - ☐ Date and time samples were placed in the incubator
 - ☐ Date and time samples were removed from the incubator
 - ☐ Identity of the person who read the results

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- (3) According to your Senior Quality Manager and Senior Director of Compliance, following the in-house incubation of the swab samples, the samples were sent to your contract laboratory for sterility testing; however, the associated records, including the third-party sterility test results, could not be located.
- (B) On August 21, 2026, during aseptic setup of the (b) (4) filling line for Biotin 0.5 mg/mL (Lot # H17A05-26), Chamber (b) (4) (Material Chamber) (b) (4) were (b) (4) exposing the (b) (4) surfaces to the ISO 7 environment. Subsequently the (b) (4) were (b) (4) without disinfecting the exposed (b) (4) surfaces, thereby reintroducing ISO 7 environmentally exposed surfaces into the ISO 5 critical area.
- (C) Your firm has not adequately established a visual inspector qualification program to demonstrate that personnel can consistently and reliably detect microbial growth during the visual inspection of media-filled units.
- (1) Your challenge qualification (b) (4), contain (b) (4) prepared with (b) (4) in (b) (4) vials and (b) (4). Your firm has no documented scientific justification for the use of (b) (4) a surrogate for actual microbial contamination/turbidity.
 - (2) There is no documented justification for the number, type, and distribution of positive units to demonstrate reliable contamination detection in media fills filled in (b) (4) vials.
 - (3) (b) (4) vials are used to simulate your (b) (4) mL and (b) (4) mL vialing process during aseptic process simulation (APS). You have not evaluated whether turbidity can be adequately detected in these vials.
- (D) Your 2026 smoke studies, conducted as per PRO-029-01, Smoke Study Protocol, and PRO-029-03, (b) (4) Airflow Visualization Protocol, did not adequately qualify unidirectional airflow or demonstrate first air and acceptable airflow patterns during critical operations. For example:
- (1) Airflow patterns could not be adequately assessed in multiple (b) (4) chambers and the (b) (4) - HEPA-filtered unidirectional airflow unit due to obstructions, glare, inadequate smoke introduction technique, and/or camera angle limitations (e.g. (b) (4) Chamber (b) (4) video; (b) (4) video).
 - (2) In (b) (4) Chamber (b) (4) turbulent eddies were observed near a (b) (4) (video time point:

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~3:26-4:22), and smoke was observed exiting and briefly re-entering the chamber near the top when the (b) (4) were (b) (4) during setup (video time point: ~4:40-4:55). (3) The studies simulated routine activities, including line setup, loading of vials, stoppers and caps, and cleaning; however, the only corrective intervention evaluated was removal of a vial from the filling line using (b) (4). Your firm did not provide an adequate assessment demonstrating that the interventions selected represent reasonably foreseeable corrective interventions and worst-case aseptic manipulations during production. The affected equipment includes: 2 (b) (4) in Suite (b) (4) housing the (b) (4) filling line used for sterile drug products such as Myer's Cocktail, NAD+ (β-Nicotinamide Adenine Dinucleotide) 100 mg/mL Injection, and MICC Injection. (b) (4); HEPA-filtered unidirectional airflow enclosures (LAFW-(b) (4) LAFW-(b) (4) LAFW-(b) (4) in Suite (b) (4), housing (b) (4) automated fillers (b) (4), and (b) (4) used for sterile drug products such as Niagen 100 mg/mL, Olympia Mineral Blend, and L-Taurine. Your smoke study report, PRO-029-02, Smoke Study Protocol: FINAL REPORT (approved 02 June 2026), and RPT-PRO-029-03, (b) (4) Airflow Visualization Report (approved 07 August 2026), both concluded that the smoke studies successfully demonstrated unidirectional airflow during dynamic operations.					
OBSERVATION 3 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, (B) Batch record review of Myer's Cocktail (Lot # G27A05-26, Exp. 26 Nov 2026) revealed that equipment set-up of the (b) (4) filling line, located inside the ISO 5 (b) (4) in Suite (b) (4) began on 30 July 2026 at 08:01 and was completed by Sterile Tech (b) (6), (b) (7)(C) at 08:06 on 30 July 2026 — a total elapsed time of five minutes. However, set-up encompassed installation of (b) (4) chambers: (b) (4) where each require multiple set up steps. For example, the (b) (4) chamber alone required the installation of multiple components, including the (b) (4), and other associated parts.					
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(C) Visual inspectors did not perform via (b) (4) as required by Section 9.3 of SOP-007, <i>Visual Inspection of Sterile Drug Products</i>, and inspection steps performed in practice differed from those written in the procedure. (1) On August 20, 2026, Sterile Tech (b) (6), (b) (7)(C) was observed conducting visual inspection of Amino Blend (Lot # H11A03-26) and failed to perform vial (b) (4). When subsequently asked to describe the inspection procedure, Sterile Tech (b) (6), (b) (7)(C) was again unable to identify vial (b) (4) as a required step. (2) On August 21, 2026, Sterile Tech (b) (6), (b) (7)(C) was observed performing visual inspection of Biotin 0.5 mg/mL (Lot # H17A05-26) and similarly failed to perform vial (b) (4). (D) On September 1, 2026, the (b) (4) (Equipment ID: (b) (4)) was observed loaded with (b) (4) on August 28, 2026. Notably, the (b) (4) was loaded with (b) (4) on (b) (4) (b) (4); however, your currently approved procedure, SOA-040-01, <i>Sterilization Load Configurations</i>, effective 05 June 2026, specifies a (b) (4) load pattern diagram of only (b) (4).			
OBSERVATION 4 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, the (b) (4) visual inspection qualification (b) (4) used to qualify personnel performing 100% visual inspection of injectable drug products are not adequately characterized or designed to challenge inspectors' ability to detect particulates at or near the threshold of visual detectability. For example: (A) Your firm has not established the size or size range of the particulate defects contained in the qualification units intended to challenge visual inspectors to detect the smallest contaminants possible for an inspector with 20/20 vision. Although (b) (4) defect vials containing particulates were submitted for size characterization, the analysis was performed using the particle-size distribution method described in USP <429>, as documented in the Certificates of Analysis. The resulting data do not establish the size of the individual particulate defect contained in each qualification unit. (B) No written procedures or records exist documenting the preparation and contents of each particulate			
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defect unit, including particulate type, size or size range, and method of preparation. This information is known only to the individual who prepared the qualification (b) (4)

OBSERVATION 5

The written stability program for drug products does not include reliable, meaningful and specific test methods.

Specifically, your firm assigns a (b) (4) beyond-use date (BUD) to Sermorelin Acetate 0.9 mg/mL Injection based on your contract laboratory stability study. However, your firm failed to provide adequate demonstration that the analytical procedure can detect relevant degradation-related changes. Your method validation report for Sermorelin Acetate, approved on August 22, 2025, does not include a mass balance assessment to demonstrate that the analytical method can adequately account for the drug substance and its degradation products, supporting the method's stability-indicating capability and reliability.

OBSERVATION 6

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

- (A) Your firm utilizes (b) (4) QA-access-controlled cabinets for the storage of sterilized machine (b) (4) parts and accessories. (b) (4) . During inspection of these cabinets (b) (4) components, including a stopper bowl that directly contacts product stoppers, were observed without sterilization-status labels. The components lacked information identifying the applicable (b) (4) and sterilization date needed for personnel to determine whether the established sterile hold time had been exceeded.
- (B) Sterilization-status labels are generated by operators; however, the firm did not demonstrate a system for reconciling generated labels to the individual equipment parts associated with each sterilization cycle.

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OBSERVATION 7

Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

- (A) SOP-035, *Procurement, Receipt, and Inspection of Incoming Components and Materials*, does not include a sampling plan specifying the number of containers to be sampled per shipment. According to the Senior Supply Chain Manager, (b) (4) sent from your (b) (4) warehouse to your facility for sampling. Additionally, no documentation exists for the sampling performed.
- (B) Your firm failed to perform a specific identity test that includes a methanol limit test on each container of each lot of ethyl alcohol used as a pharmaceutical ingredient. On May 12, 2025, your firm received (b) (4) bottles of (b) (4) Ethyl Alcohol (b) (4) Proof (Batch # (b) (4)); (b) (4) sampled, and methanol limit testing was not performed. This lot was used in the production of T-105 Injection (Papaverine Hydrochloride 30 mg/mL; Phentolamine Mesylate 1 mg/mL; Alprostadil 0.01 mg/mL), Lot #G08A10-26, BUD 04 JUL 2027.
- (C) Your firm failed to test each container of each lot of glycerin, used as a pharmaceutical ingredient, for diethylene glycol (DEG) or ethylene glycol (EG) contamination. Your firm did not provide a scientifically sound justification, supported by statistical analysis, for reduced sampling. On September 25, 2025, your firm received (b) (4) bottles of (b) (4) Glycerin, NF (b) (4) ((b) (4)) (Lot # (b) (4)); however, (b) (4) sampled and tested for this shipment. Additionally, Lot # (b) (4) was tested only for Identification A and was not tested for DEG and EG prior to release for use. This lot was used in the production of Glycerin 48% / Lidocaine 0.33% Injection (Lot #E20A10-26; BUD 10 JAN 2027).

OBSERVATION 8

Each component is not added to the batch by one person and verified by a second person..

Specifically, a review of the batch record for Myer's Cocktail (Lot # (b) (4) , Exp (b) (4)) revealed that ingredients were added between (b) (4) on July 29, 2026, with no documented contemporaneous

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verification recorded after each individual addition. Instead, a single verification timestamp of (b) (4) was documented for this manufacturing step, more than two hours after the last ingredient was added.

***DATES OF INSPECTION**

8/20/2026(Thu), 8/21/2026(Fri), 8/24/2026(Mon), 8/25/2026(Tue), 8/26/2026(Wed), 8/27/2026(Thu),
8/28/2026(Fri), 8/31/2026(Mon), 9/01/2026(Tue), 9/02/2026(Wed), 9/03/2026(Thu)

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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."