DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/28/2025-8/8/2025* FEI NUMBER 3009724085

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark Mikhael, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Olympia Pharmaceuticals	6700 Conroy Rd Ste 155
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orlando, FL 32835-3515	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 I OBSERVED:

OBSERVATION 1

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

Specifically,

A. During the observation of air visualization study SO# FL-OYPP232701P-1 for your dynamic aseptic filling operation in Buffer Room (b) (4), Unit ID: (b) (4), the following deficiencies were noted:

1. The setup of vials, stoppers, and caps at the edge of the hood results in air arching and dragging, which prevents these critical components from receiving first air.
2. The filler needle is (b) (4) oriented within a (b) (4) laminar flow hood blocking unidirectional airflow.
3. The viable air monitor's functionality was not demonstrated during operation, therefore, there is no evidence to show that its placement could affect airflow in the critical area.

B. Dynamic FPC50 air visualization study:

1. Air visualization studies show air arching over stoppers, caps, and seals, indicating that these critical components are not receiving first air.
2. The filler needle is (b) (4) oriented within a (b) (4) laminar flow hood blocking unidirectional airflow.
3. The auto-filler's setup, with the tubing that carries the sterile solution to the needle, is not

AMENDMENT 1

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included in the air visualization study, preventing an accurate assessment of airflow in the critical zone.

C. (b) (4) Dynamic and Loading air visualization study:

1. Air arching was observed over open vials and incompletely seated, stoppered vials.
2. Turbulence and smoke drag were present in the middle of the turntable, within the critical zone of the open vials.
3. The video angle was inadequate to fully assess the filling and stoppering processes.

OBSERVATION 2

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 firm lacks assurance that the light conditions are adequate for the visual inspection of amber-colored vials. Specifically:

1. Your procedure, SOP-007 "Visual Inspection of Sterile Drug Products" (version 13, effective 07/03/2025), requires light intensity to be measured and documented (b) (4) use, with a specified range of (b) (4) to (b) (4) Lux. This range is not justified as being adequate for the effective inspection of amber vials.
2. Furthermore, while your firm claims that light levels at the working height are consistently within an acceptable range of (b) (4) to (b) (4) Lux, your current procedures and documentation do not require or demonstrate the measurement of light intensity at the actual working height of the inspection station. The light measurements are performed at a fixed reference point on the table surface, which does not provide assurance that the illumination

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level at the point of inspection is consistently maintained.

3. As per your procedure SOP-007, the (b) (4) should contain particulate defects that are challenging for inspectors to detect. However, during my review of (b) (4) ID: (b) (4), I found that the "inherent particle," "intrinsic particle," and "vial imperfection" defects were too large and obvious to serve as a suitable challenge during qualification.

OBSERVATION 3

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

Specifically,

A. During the (b) (4) cleaning and disinfection of the ISO 5 Laminar Airflow Workstations (LAFWs) and Auto Filler Systems (AF) in Cleanroom 305 on 8/5/2025, I observed three cleaning operators exhibiting poor cleaning practices. Specifically, after the interior surfaces of the LAFWs (LAFW (b) (4), LAFW (b) (4), and LAFW (b) (4)) had been disinfected, I observed the cleaning operators stepping inside the LAFWs area and making contact with the cleaned interior walls of the LAFWs by leaning against them with their garments (backs, shoulders, or arms) while cleaning the auto-filler units.

B. Additionally, when the operator was cleaning the exterior walls of the LAFW (b) (4) I observed the operator's gloved hand contact the previously disinfected LAFW (b) (4) interior wall. This contact occurred when the operator used the side wall of the LAFW for support while reaching to clean the upper lateral exterior wall.

C. On July 30, 2025, I observed that a package of (b) (4) wipes was left open and exposed to the ISO 7 cleanroom 305 environment. I then observed an operator use a wipe from this package to perform cleaning inside the ISO 5 hood during the disassembly of Auto Filler (b) (at the completion of Olympia Vita-Complex, lot# G28A02-25.

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*DATES OF INSPECTION

7/28/2025(Mon), 7/29/2025(Tue), 7/30/2025(Wed), 7/31/2025(Thu), 8/01/2025(Fri), 8/04/2025(Mon), 8/05/2025(Tue), 8/07/2025(Thu), 8/08/2025(Fri)

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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."