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 ORAPHARM2_RESPONSES@fda.hhs.gov	5/14/2024-5/29/2024* FEI NUMBER 3009724085

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark W. Mikhael, PharmD, CEO	
FIRM NAME Olympia Compounding Pharmacy	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

Drug products failing to meet established specifications are not rejected.

Specifically, your firm released and distributed drug product MICC (methionine 25mg, inositol 50mg, choline 50mg, cyanocobalamin 330 mcg) Lot (b) (4), BUD: 08 JUL 23 that failed finished product testing for low cyanocobalamin assay at 87.4%. On 03/24/2023 Lot# (b) (4) was rejected and dispositioned to be destroyed by your quality unit but your firm already began distributing this lot 10 days prior on 03/14/2023. A total of (b) (4) vials of lot (b) (4) were distributed from 03/14/2023 through 05/08/2023.

***This is a repeated observation from the previous FDA Inspection dated 2/14-2/23/22.**

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,

1. Your firm failed to conduct a Performance Qualification (PQ) where your firm establishes all filling parameters including but not limited to cap placement involving circular vibrator speed and the cap crimping station involving crimp time and adequate in-process sampling for all your drug products produced on the (b) (4) Filling Machines.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kayla V Sprague, Investigator Jessica P Mcalister, Investigator Libia M Lugo, Investigator Logan T Williams, Investigator X	5/29/2024

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A. On 5/14/24, (b) (4) Filling Machine (b) faulted during the production of Vitamin D3 50,000 IU/mL lot (b) (4) BUD 09 NOV 24 due to issues with the crimping station. Deviation # D-2024-017 was opened and the investigation is on-going.

B. On 5/15/24, during the filling operation for Lysine lot (b), BUD: 31 AUG 24 on the (b) (4) Filling Machine (b) (4) the line was stopped numerous times for defective crimping. According to your firm you produced (b) (4) vials in total prior to stopping production. Two hundred twenty-four (224) vials were discarded. Deviation # D-2024-022 was opened and the investigation is on-going.

C. On 5/15/24, I observed vials of Semaglutide 5mg/mL (3mL) lot # (b) (4), BUD 03 SEP 24 that were visually inspected by your firm with fill weight discrepancies. Your firms in-process sampling (every (b) (4)) for fill weight is inadequate as it fails to include measuring the volume with a calibrated instrument and instead you only conduct a visual check for the volume filled allowing for variability between operators.

2. Your firm failed to establish a procedure for the assembly/disassembly of the (b) (4) Filling Machines following cleaning operations. In addition, your firm's preventative maintenance conducted on (4) basis is inadequate as it fails to incorporate the inspection and potential replacement o the manual-seals, slide bearings and timing belts which are outlined in the (b) (4) Filling Machine manual.

OBSERVATION 3

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

Specifically,

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	Kayla V Sprague, Investigator Jessica P Mcalister, Investigator Libia M Lugo, Investigator Logan T Williams, Investigator	X Jessica P Mcalister Investigator Signed L Mcalister-S Date Signed 0 90:10:	5/29/2024

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1. Your firm failed to validate your (b)(4) sterilization process which incorporates the use of (b) (4) utilizing biological indicators within the lyophilizer.

2. On 5/14/24 in preparation for lyophilizing a drug product the next day per SOP #P-806, Operation and Maintenance of the Lyophilizer, Section 8.6.5 your firm conducted (b) (4) cleaning and sterilization of the interior chamber from 17:10pm until 17:30pm with (b) (4) RTU and (b) (4) spraying the internal surfaces.

   On 5/15/24 at 11:31am (approximately 19 hours later with no established hold time) during visual inspection of the interior chamber of your lyophilizer I observed residual liquid on multiple product shelves. Your firm was unable to provide evidence on what the residual liquid was and that it does not introduce contamination to your lyophilization cycle.

3. Your firm failed to include the stopper chute (product contact surface) within your cleaning validation/sterilization of the (b) (4) filling machine therefore there is no documentation ensuring the residual detergent ((b) (4), part number 1D1008) from your cleaning operation is adequately removed.

   ***This is a repeated observation from the previous FDA Inspection dated 2/14-2/23/22.**

4. On 5/15/24, during the production of Lysine, lot # (b) (4), BUD: 31 AUG 24 within Cleanroom C (ISO 7) we observed the wheel of a stainless-steel cart and the stainless-steel external base of your lyophilizer to contain an amber colored residue. Your firm opened Deviation # D-2024-019. In addition, within Cleanroom CR (ISO 7) where bulk sterilization occurs chipped/peeling caulking or paint was observed on the ceiling.

OBSERVATION 4

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

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Specifically, your firm failed to use a broth containing disinfectant neutralizers for your viable surface swab samples. Your firm conducts viable surface swab samples on the stopper bowl (product contact surface), filling needle (product contact surface) and tube transport port.

OBSERVATION 5

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

Specifically, your firm does not assure that worst-case processing conditions for line speed are met as outlined in "Verification Protocol for Process 1 by Aseptic Process Simulation". Per protocol, the 30mL size vial should be filled at the (b) (4) vials per minute (vpm) and the 10mL size vial should be filled at the (b) (4) vials per minute. Vials per minute is an output of all parameters set up on the (b) (4) filler. No vial per minute monitoring is performed during execution of aseptic processing simulations. In addition, on 5/14/2024, during observation of sterile filling for 30mL L-Lysine lot (b) (4), the vials (b) (4) was observed to be (b) (4) (b) (4) which is slower than the worst-case scenario outlined in the aseptic process simulation protocol.

OBSERVATION 6

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, your firm failed to investigate complaints received by your complaint intake team, including complaints related to apparent adverse drug events. Currently, your firm has identified 167 received complaints from 3/13/2024 - 5/22/2024, and is working backwards by date to retrospectively capture all missed complaints.

In addition, these complaints were restored from a "Deleted Items" folder within the complaint intake

team's email folders. Additionally, your firm did not document all complaints as required by complaint procedure "Complaint Handling, Drug Safety, and Surveillance". Complaints not investigated include but are not limited to:

a. Glutathione 200mg/mL lot (b)(4), BUD 5/13/2024 – this complainant stated that they had an adverse reaction and thou it they were going into cardiac arrest.

b. B12 Methylcobalamin 5mg/mL lot (b)(4), BUD 5/12/2024 – this complainant stated a patient came into the clinic and received an injection of B12 and had to be rushed to the hospital.

c. Sodium Bicarbonate 8.4% lot (b)(4), BUD 2/19/2024 – this complainant stated that the sodium bicarbonate precipitated out when it was mixed with Lidocaine. They stated they have performed this many times with no issues.

d. Tri-Immune unknown lot number and unknown BUD – this complainant stated that the vial was warm when it was received. This product requires storage from 2-8 degrees C. Your firm responded from an Olympia Pharmacist email stating that the product was okay to use.

e. Semaglutide unknown lot and unknown BUD – complainant stated they've had a multitude of patients and staff members expressing dissatisfaction in the effectiveness of the firm's semaglutide.

f. Tirzepatide Injectable unknown lot and unknown BUD – complainant stated that the product was not controlling blood glucose effectively.

OBSERVATION 7

Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, drug products were compounded and not identified on your reports dated June 2023 and December 2023, including, but not limited to:

- ☐ PGEl (alprostadil) 40 mcg/mL injection
- ☐ PGE3 (alprostadil) 150 mcg/mL injection
- ☐ Sodium tetradecyl sulfate 0.1% injection

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☐ Sodium tetradecyl sulfate 0.3% injection
☐ Zinc sulfate 10 mg/mL injection

***This is a repeated observation from the previous FDA Inspection dated 2/14-2/23/22.**

***DATES OF INSPECTION**

5/14/2024(Tue), 5/15/2024(Wed), 5/16/2024(Thu), 5/17/2024(Fri), 5/20/2024(Mon), 5/21/2024(Tue), 5/22/2024(Wed), 5/23/2024(Thu), 5/29/2024(Wed)

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	Kayla V Sprague, Investigator Jessica P Mcalister, Investigator Libia M Lugo, Investigator Logan T Williams, Investigator	X Jessica P Mcalister Investigator Signed By: Jessica L. Mcalister -S Date Signed: 05-29-2024 10:10:26	5/29/2024

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."