DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	6/23/2025-7/3/2025*
	FEI NUMBER 3003434972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Craig (nmi) Mastenbaum, , Senior Vice President cGMP Operations

FIRM NAME	STREET ADDRESS
Wedgewood Connect, LLC	17 Great Oaks Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Jose, CA 95119-1359	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

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 written procedure, SOP 3.030 Environmental Monitoring, v15.0, is inadequate regarding the following:

1) The procedure instructs personnel gowning sample collection in a manner that can produce false negative results. For example, per procedure your primary (ISO 5) and secondary (ISO 7) compounding production operators may collect EM gowning samples from each other. On **June** ~~July~~ 24, 2025, observation of gowning sample collection following production of Moxifloxacin in Balanced Salt Solution (BSS) 1 mg/mL Injection Solution, Lot Numbe (b) (4), found that, per procedure, the support operator sanitized their gloves prior to collecting samples from primary operator's glove fingers and sleeves. Directly after, glove fingertip and sleeve samples were collected from the secondary operator. Glove sanitization prior to sample collection is instructed in SOP 3.030, yet the observed practice of secondary operator's glove sanitization prior to sample collection can produce false negatives.

2) The procedure does not instruct surface sample collection from all areas within the critical zone of

AMENDMENT 1

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	Jolanna A Norton, Investigator Matthew R Clabeaux, Investigator	X Matthew R Clabeaux Investigator Signed By: Matthew R. Clabeaux - S Date Signed: 07-03-2025 14:58:18	7/3/2025

your ISO 5 Laminar Flow Hoods where sterile human compounded drug is produced. For example, your Final Report for Addendum of Environmental Monitoring Performance Qualification, dated March 7, 2024, identifie (b) (4) sampling sites for ISO 5 work areas, including the (b) (4) where (b) (4) (b) (4) and (b) (4) occur. SOP 3.030, "Environmental Monitoring", only instructs sample collection from (b) (4) sites; (b) (4) Sampling Area" and (b) (4) Sampling Area." There is no assurance that current environmental monitoring per procedure 3.030, adequately detects microbial contamination in the "Critical zone", potentially compromising the sterility assurance of your compounded drug products.

OBSERVATION 2
Employees are not given training in the particular operations they perform as part of their function.

Specifically,

Your visual inspectio (b) (4) for 2mL vials used to qualify VI inspectors does not include representative vials for white particle defects. There is no assurance that personnel qualified for 100% visual inspection can identify all known defects found in your sterile human compounded drug product, Moxifloxacin 1mg/mL Injection. Your written procedure, SOP 9.170 Visual Inspection v6.0, lists white particles as a product defect category, and white particles are categorized as a major defect for Moxifloxacin 1mg/mL in 2mL vials.

OBSERVATION 3
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

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Craig (nmi) Mastenbaum, , Senior Vice President cGMP Operations	
FIRM NAME Wedgewood Connect, LLC	STREET ADDRESS 17 Great Oaks Blvd
CITY, STATE, ZIP CODE, COUNTRY San Jose, CA 95119-1359	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Your firm's Addendum of Environmental Monitoring Performance Qualification, dated March 7, 2024, establishes sampling sites for ISO 5 environmental monitoring in Biosafety Cabinets (BSC) and Laminar Flow Hoods (LAFW). However, this validation study failed to include LAFW equipment ID E-0083-W, which was used in the manufacture of Moxifloxacin in Balanced Salt Solution (BSS) 1 mg/mL Injection Solution, 1 mL in 2 mL Vial, Lot Numbe (b) (4), manufactured on August 26, 2024.

The exclusion of manufacturing equipment from your environmental monitoring validation compromises your ability to demonstrate that established procedures adequately control the manufacturing environment and ensure product quality.

OBSERVATION 4

The written stability program does not assure testing of the drug product in the same container-closure system as that in which the drug product is marketed.

Specifically,

You did not perform finished product stability studies for your sterile human compounded drug, Moxifloxacin in Balanced Salt Solution 1mg/mL Injection in 2mL vial, following supplier change for 2mL vial finished product container. Change control, CC-009-2024, dated August 24, 2024, did not include evaluation of finished drug product stability to demonstrate that product quality of sterile human drug product is maintained throughout expiry in the new containers.

OBSERVATION 5

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

Specifically,

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Your firm has released the following batches manufactured in ISO 5 conditions your investigations confirmed bacterial contamination:

Lot	Product	Production Date	Sample Location	Excursion
(b) (4)	Cyclosporine 1% in Corn Oil 15mL in a 15mL Dropper Bottle	(b) (4)	(b) (4) Operator (b) (4) Sleeve	1 CFU *Micrococcus Luteus*
	Cyclosporine 2% in Corn Oil, Ophthalmic Solution, 15 mL in a 15mL Dropped Bottle		(b) (4) Operator (b) (4) Glove	1 CFU *Litchfieldia cheonanensis*

These lots were released after your independent laboratory testing confirmed bacterial contamination and they represent a failure in your sterile manufacturing controls to effectively prevent microbiological contamination.

***DATES OF INSPECTION**

6/23/2025(Mon), 6/24/2025(Tue), 6/25/2025(Wed), 6/26/2025(Thu), 6/27/2025(Fri), 6/30/2025(Mon), 7/01/2025(Tue), 7/02/2025(Wed), 7/03/2025(Thu)

X Jolanna A Norton
Investigator
Signed By: Jolanna A. Norton -S
Date Signed: 07-03-2025 14:58:44

AMENDMENT 1

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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."