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	11/1/2023-11/17/2023* FEI NUMBER 3003434972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Craig Mastenbaum, General Manager

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

Written records are not always made of investigations into unexplained discrepancies.

Specifically,

A) Investigations are not always performed for environmental/personnel monitoring excursions within the ISO-5 and ISO-7 (action limits of (b) (4) and (b) (4), respectively) areas as required by SOP 3.030, Environmental Monitoring, Version: 10, Date Effective: 09/22/2023. The following are examples where investigations were not performed to determine a root cause, product impact, and the need to implement a CAPA to prevent recurrence:

Date of Sampling	Location	ISO	Result	Organism (if identified)	Associated Product and Lot Number
09/26/2022	(b) (6), (b) (7)(C) (b) (4)	5	1cfu	Fungal (Unable to ID)	Cyclosporine 0.2% in Corn Oil, 15mL Lot #(b) (4)
03/10/2022	(b) (6), (b) (7)(C) (b) (4)	5	1cfu	*Kocuria rhizophila*	Demecarium Bromide 0.125% Ophthalmic Solution, Lot #(b) (4)
03/10/2023	(b) (6), (b) (7)(C) (b) (4)	5	1cfu	*Micrococcus luteus*	Tacrolimus 0.02% in Corn Oil, 15mL Lot #(b) (4)

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EMPLOYEE(S) SIGNATURE
Jeffrey P Raimondi, Consumer Safety Officer
Anney Lin, Investigator
Andrew Le, Investigator

X Jeffrey P Raimondi Consumer Safety Officer Signed By: Jeffrey P. Raimondi -S Date Signed: 11-17-2023 1 :20:10

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04/14/2023	(b) (6), (b) (7)(C) (b) (4)	5	1cfu	*Bacillus altitudinis*	Cyclosporine 2% Ophthalmic Suspension, 15mL Lot #(b) (4)
05/01/2023	(b) (6), (b) (7)(C) (b) (4)	5	1cfu	*Kocuria palustris*	Buprenorphine 0.6 mg/mL Injection Solution, Lot #(b) (4)
11/03/2022	(b) (6), (b) (7)(C) (b) (4))	7	13cfu	*Staphylococcus aureus* and *Staphylococcus epidermidis*	Tacrolimus 0.03% in Corn Oil, 15mL Lot #(b) (4) Tacrolimus 0.03% in Corn Oil, 5mL Lot #(b) (4) , and Tacrolimus 0.02% in MCT Oil 10mL Lot #(b) (4)
07/06/2023	(b) (4)	7	TNTC	Unable to ID	No production in this room
08/04/2023	(b) (6), (b) (b) (4))	7	13	*Rhizobium* species	Tacrolimus 0.03% Ophthalmic Suspension, 15mL Lot #(b) (4) and Tacrolimus 0.02% in MCT Oil, 5mL Lot #(b) (4)

B) Investigation into the turbid media fill 15ml bottle under OOS00041, for lot# (b) (4) did not include identification of the microorganism recovered. Additionally, the operator who performed this media fill was not requalified through performance of an additional media fill, and to date, this operator has filled approximately (b) (4) batches of sterile human and animal drug products.

C) Complaint investigations do not include evaluation of retain samples as required by procedure 5.031, Customer Complaints, Version: 5.0, Date Effective: 06/01/2022. The following are examples were retain samples were not evaluated:

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Complaint Number	Due Date	Product	Lot Number	Description
C-350-2022	10/20/2022	Cyclosporine 2% in Corn Oil-15mL	(b) (4)	Fuzzy layer on the bottle that looks like crystals
C-650-2022	02/14/2023	Cyclosporine Corn 2% Ophth 15ml	(b) (4)	Medication looks cloudy and has particulates
C-147-2023	06/28/2023	Cyclosporine Corn 2% Ophth 15ml	(b) (4)	Medication has chunks in it
C-266-2023	08/17/2023	Cyclosporine Corn 1% Ophth 15ml	(b) (4)	Black spec inside bottle

OBSERVATION 2

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

Specifically, disinfectant efficacy studies have not been performed for the (b) (4) , and the (b) (4) cleaning solutions used within your ISO-5 and ISO-7 aseptic processing areas, to confirm these solutions are appropriate for use within these areas and against all surface types they are used on. The ISO-5 and ISO-7 aseptic processing areas are used for human and animal drug production.

OBSERVATION 3

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

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Specifically,

A) Surface sampling locations within the ISO-5 areas for processing human and animal drugs are not supported with appropriate studies.

B) The non-viable particle monitoring probes within the ISO-5 Biological Safety Cabinets (BSC) (such as (b) (4) , and (b) (4) and Laminar Airflow Hoods (LAF) (such as (b) (4)) are not pointed into the direction of the airflow. Within the BSCs, probes were observed pointing towards the operator and perpendicular to the direction of airflow. The probes within the LAF were observed pointing the same direction as the airflow.

C) The non-viable particle monitoring probes within the ISO-7 cleanrooms such as rooms 120 and 121 are not pointed into the direction of the airflow. Rather these probes are hanging from the ceiling and pointed towards the floor.

D) The ISO-7 rooms containing the ISO-5 filling BSCs and LAFs are only required to be tested for viable (surface and active air) microorganisms (b) (4) as required by SOP 30.030, Environmental Monitoring, Version 10, Effective Date: 09/22/2023, Table 2: Frequency of Sampling in ISO-7 Classifications. The ISO-7 rooms are not required to be tested each day the ISO-5 BSC and LAFs are in use.

OBSERVATION 4

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

Specifically,

A) Requalification of the (b) (4) Sterilization Process for (b) (4) Loads (b) (4) Bottle Formats) in the

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(b) (4) (b) (4) Model (b) (4), Equipment ID# E-0832-W, performed 11/11/2022 failed to meet the minimum requirement of (b) (4) on (b) (4). (b) (4) reported a value of 120.05 during the qualification. The acceptance criteria states the minimum temperatures from all (b) (4) during sterilization phase must be (b) (4).

Additionally, (b) (4) failed its pre- and post- calibration check and was used during the requalification.

Although the requalification occurred 11/11/2022, to date, the final report has not been approved by the quality unit.

This (b) (4) is used to sterilize human and animal drug products inside (b) (4) bottles, prior to these products being aseptically filled. Between 11/11/2022 and now, there have been approximately (b) (4) batches of drug product sterilized with this equipment.

B) Operators were observed blocking first pass air on 11/01/2023 while filling the following drug products:
   - Tacrolimus 0.02% in Corn Oil, Ophthalmic Solution, 15 mL lot #(b) (4)
   - Cyclosporine 2%/Tacrolimus 0.2% in Corn Oil, Ophthalmic Solution, 15 mL lot #(b) (4)

C) Airflow visualization studies are inadequate for the following reason:

1. The generated smoke was not robust enough to show the flow of air.

2. Smoke was not always observed to be directly above the area where the activity was occurring during video "(b) (4) (b) (4) Process APR2023". Smoke appeared to be in the back corner of the BSC while operator activities were occurring in the center of the BSC.

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3. Unidirectional airflow was interrupted with eddy currents detected at timepoint (b) (4) during video "(b) (4) Dynamic Basic APR2023".

4. While smoke studies were performed for (b) (4) among the ISO-5 hoods, the entire filling process including setup and filling operations have not been evaluated within each hood under dynamic conditions as part of qualification.

OBSERVATION 5

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

Specifically, the visual inspection qualification program is inadequate. There is no assurance that personnel qualified for 100% visual inspection can identify all known critical defects found in your sterile drug products. Operators must score at least a (b) (4) on the qualification, however, the Visual Inspection Qualification Test document shows (b) (4) out of (b) (4) operators who perform visual inspection failed to identify critical defects such as particles during their qualification.

OBSERVATION 6

The quality control unit lacks the responsibility and authority to approve and reject all in process materials and drug products.

Specifically,

A) An Acceptable Quality Limit (AQL) for visual inspection is not performed for sterile drug products.

B) There is no test kit for the (b) (4) vial, rather operators are qualified using (b) (4) vial test kits. The (b) (4) vial is the size of Moxifloxacin 1mg/mL drug product and represents the (b) (4) vial sized

used for drug products. Additionally, there are no test kits for operator qualification for any product placed in droppers, such as the Cyclosporine and Tacrolimus drug products.

C)The visual inspection qualification (b) (4) (b) (4) and (b) (4) contain vials (b) (4) -(b) (4) with a (b) (4)" on the (b) (4) identifying them as containing particles. Personnel performing visual inspection of sterile drug products are required to correctly identify the defects during qualification. These vials (b) (4)(b) (4) with a "(b) (4)" inform the operator that the vial contains a particulate.

D)A standard timer is not used to ensure operators visually inspect each vial and dropper for (b) (4) (b) (4) against (b) (4) and(b) (4) . Procedure 9.170, Visual Inspection, Version: 2, Effective Date: 06/26/2020 requires operators to visually inspect each unit for (b) (4) (b) (4) against each (b) (4) .

OBSERVATION 7

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, your firm has designated hazardous (HD, room 121) and non-hazardous (NHD, room 120) production areas, however, it was noted both forms of drug products could be compounded at the same time within separate BSCs in the formulation room (room 118). For example, on 07/06/2023 Moxifloxacin 1 mg/mL in Sterile Balance Salt Solution (BSS) lot #(b) (4) (which is a NHD drug) was compounded at the same time as Tacrolimus 0.02% in Corn Oil lot #(b) (4) (which is a HD).

OBSERVATION 8

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

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Specifically, the following information is not found on your drug product labels:

A) The name of the outsourcing facility.

Example of your drug product labels that do not contain this information:

- Moxifloxacin 1 mg/mL in Sterile Balanced Salt Solution Injection, 1 mL in 2 mL vial (NDC 79926-068-05)

***DATES OF INSPECTION**
11/01/2023(Wed), 11/02/2023(Thu), 11/03/2023(Fri), 11/06/2023(Mon), 11/07/2023(Tue), 11/09/2023(Thu), 11/13/2023(Mon), 11/15/2023(Wed), 11/17/2023(Fri)

X Anney Lin
Investigator
Signed By: 2003914351
Date Signed: 11-17-2023 14:20:44

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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."