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	11/16/2021-12/3/2021* 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

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A) You failed to establish a written procedure for assessment and disposition of critical reject units identified during process validation and operator qualification aseptic media fills. Your assessment of the (b)(4) aseptic media fills in (b) (4), conducted since May 13, 2020, is inadequate. For example, 49 of the (b)(4) media fill batches were documented with critical rejects, but only rejected units from 19 of those media fills were submitted for incubation and assessment, while rejected units from 30 batches were not.

B) You failed to establish a written procedure for use and maintenance of the (b) (4). Your investigation of black particles found during visual inspection of sterile compounded drug product, Cyclosporine 2%, Ophthalmic Suspension 15 ml, Lot (b) (4), determined the (b) (4) to be the source of particles, and the root cause to be lack of SOP to instruct operators on the proper use of the (b) (4).

C) You failed to fully follow your written procedure for corrective and preventative action, SOP 9.030 v1.0 by initiating a CAPA for unfavorable customer complaint trends regarding particles and clogged bottles reported in sterile compounded ophthalmic products. For example, since April 2021 you received 7 customer complaints for particles, and 17 customer complaints for clogged bottles, prior to initiating 21CAPA001, on October 8, 2021.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jolanna A Norton, Investigator Lisa Shin, Investigator	X Jolanna A Norton Investigator Signed By: Jolanna A. Norton -S Date Signed: 12-03-2021 15:57:35	12/3/2021

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OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

A) You failed to conduct investigations to determine root cause, product quality, and corrective and preventive actions for the following customer reported issues for sterile compounded drug product:

1) Ten (10) reported complaints for particles found in multiple lots of Cyclosporine 2% in Corn Oil, Ophthalmic Solution, since July of 2021;

2) Eighteen (18) reported complaints for clogging of the bottle in multiple lots of Cyclosporine 2% in Corn Oil, Ophthalmic Solution, since May of 2021;

3) One (1) reported customer complaint for particles found in, Apomorphine HCl 3 mg/ml Injection Solution, since April of 2021;

4) One (1) reported customer complaint for clogging of the bottle in Tacrolimus 1% in MCT Oil, Ophthalmic Solution, since September of 2021.

You failed to document in Customer Complaint Forms an explanation or justification for why no investigation was needed.

B) You failed to investigate cause of non-integral unit identified during in-process evaluation of media fill units. For example, on 11/17/2021 we observed the operator identify and segregate a non-integral unit during in-process evaluation following (b) (4) incubation of Operator Qualification Media Fill of (b) (4) bottles, Lot (b) (4), Fill date (b) (4). You failed to establish in written procedure criteria for identifying non-integral units during in-process evaluation of media fill, and a requirement for assessment and disposition.

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OBSERVATION 3

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

Specifically, on 11/16/21 we observed one partially closed vial in a tray of (b) (4) vials moved from the ISO 5 LAF to a cart located in the ISO 7 filling suite during aseptic filling operations for sterile compounded drug product, Pentosan Polysulfate Sodium 250 mg/ml Injection Solution, 50 ml in 50 ml vial, Lot (b) (4), Exp 05/2022. The operator failed to identify or remove the partially closed vial from the tray until we alerted the firm. Your written procedure for filling and capping glass vials, SOP 6.080, failed to instruct review of vial closures prior to removal from ISO 5, and rejection of (b) (4) vials after moving to ISO 7.

OBSERVATION 4

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, on 11/18/2021 we observed brown residue near air return vents in (b) (4) ISO 5 certified biological safety cabinets ((b) (4)) where non-hazardous and hazardous materials are weighed out, and where non-sterile liquid bulk drug product is mixed. Cleaning performed on 11/18/2021 in (b) (4) after use to formulate non-sterile bulk drug product, Tacrolimus 0.03% in MCT oil, Lot 222-03527655, and cleaning performed on 11/17/2021 in (b) (4) after use to formulate non-sterile bulk drug product, Tacrolimus 0.02% in MCT Oil, Lot (b) (4), failed to remove the brown residue and to ensure potential contaminants are adequately removed from surfaces as instructed in your written procedure for cleaning and disinfection of ISO 5 cabinets, SOP 3.022.

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***DATES OF INSPECTION**
11/16/2021(Tue), 11/17/2021(Wed), 11/18/2021(Thu), 11/19/2021(Fri), 11/22/2021(Mon), 11/23/2021(Tue), 11/29/2021(Mon), 12/03/2021(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."