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	8/22/2022-9/15/2022* FEI NUMBER 3021934346

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lauren CML Honda, Pharmacist-In-Charge, Senior Director of Compliance

FIRM NAME	STREET ADDRESS
Valor Compounding Pharmacy, Inc DBA Valor Compounding Pharmacy	2461 Shattuck Ave
CITY, STATE, ZIP CODE, COUNTRY Berkeley, CA 94704	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile and Sterile Drug Products

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

You produced hazardous drugs without providing adequate containment and segregation to prevent cross-contamination.

Specifically,

A)On 08/22/2022 and 08/23/2022we observed the following non-sterile hazardous compounded drug products stored in (b) (4) food-grade beverage pitchers:

-Tacrolimus ((b) (4)) 0.5 mg/ml Suspension, Lot 08112022@(b) (4), Discard Date 10/6/2022
-Tacrolimus ((b) (4)) 0.5 mg/ml Suspension, Lot 08182022@(b) (4), Discard Date 10/13/2022
-Tacrolimus ((b) (4)) 0.5 mg/ml Suspension, Lot 08182022@(b)(, Discard Date 10/13/2022
-Hydroxyurea 100 mg/ml Suspension, Lot 08192022@(b) (4), Discard Date 02/15/2023

You lack assurance that hazardous drug substances do not leach into food-grade (b) (4) affecting purity and potency of drug products stored in them. You lack assurance that your cleaning agents, (b) (4) can adequately deactivate and remove hazardous substances from surfaces of food-grade (b) (4) containers.

B) On 08/22/2022 during production of non-sterile hazardous compounded drug products:

-Cidofovir 1% Ointment, Lot 08232022@(b) (4), Beyond Use Date 9/22/2022
-Hydrocortisone/Hydroquinone/Kojic Acid/Trentinoin 1%/10%/3%/0.05% Cream, Lot 08232022@(b) (4) Beyond Use Date 9/21/2022

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jolanna A Norton, Investigator Cecilia H Kieu, Investigator	X Jolanna A Norton Investigator Signed By: Jolanna A. Norton -S Date Signed: 09-15-2022 16:01:30	9/15/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	8/22/2022-9/15/2022*
	FEI NUMBER 3021934346

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Lauren CML Honda, Pharmacist-In-Charge, Senior Director of Compliance

FIRM NAME	STREET ADDRESS
Valor Compounding Pharmacy, Inc DBA Valor Compounding Pharmacy	2461 Shattuck Ave
CITY, STATE, ZIP CODE, COUNTRY Berkeley, CA 94704	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile and Sterile Drug Products

We observed the following examples of inadequate containment and segregation of clean equipment and utensils to prevent cross-contamination:

-Uncovered clean mixing bowls stored on open shelves beneath (b) (4) hood where hazardous (b) (4) drug substance, Hydroquinone USP, was weighed out.

-Uncovered clean mortars/pestles stored on open shelves below work bench where hazardous drugs are mixed and filled. A mortar and pestle taken from an open lower shelf used to (b) (4) and (b) (4) during production of Hydrocortisone/Hydroquinone/Kojic Acid/Trentinoin 1%/10%/3%/0.05% Cream.

-Uncovered clean spatulas stored next to an open container holding (b) (4) used to soak dirty equipment.

***DATES OF INSPECTION**

8/22/2022(Mon), 8/23/2022(Tue), 8/24/2022(Wed), 8/25/2022(Thu), 8/26/2022(Fri), 8/29/2022(Mon), 8/30/2022(Tue), 9/01/2022(Thu), 9/08/2022(Thu), 9/15/2022(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jolanna A Norton, Investigator Cecilia H Kieu, Investigator	X Jolanna A Norton Investigator Signed By: Jolanna A. Norton -S Date Signed: 09-15-2022 16:01:30	9/15/2022

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."