DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707 ORAPHARM1_RESPONSES@fda.hhs.gov	11/8/2021-12/2/2021* FEI NUMBER 3004562873

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Renee T. McCarthy, PharmD, Owner/Compounding Specialist

FIRM NAME	STREET ADDRESS
Valgene Incorporated dba Cape Drugs	1384 Cape St Claire Rd
CITY, STATE, ZIP CODE, COUNTRY Annapolis, MD 21409-5325	TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-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

Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically, on November 23, 2021, during daily cleaning following the completion of sterile production operations, the use of your disinfectant and sporicidal agent, (b) (4) , in the ISO 5 classified laminar flow hood was not allowed to dwell the required (b) (4) contact time, per your procedures and the cleaning agent manufacturer's use directions. Most areas of the hood work surface had a drying time of less than (b) (4) .

OBSERVATION 2

The ISO 5 classified aseptic processing areas had difficult to clean and particle-generating equipment or surface.

Specifically, your ISO 5 classified laminar airflow hood (LAFH) sits atop a bench which appears to be made of a wood-like material laminated on the top and sides. The bottom of the bench is not laminated, and the wood-like material is exposed within the ISO 7 classified "Sterile Prep" buffer room. Additionally, the front-right laminated corner of the bench is chipped such that the wood-like material is exposed, approximately less than one-half centimeter in diameter.

Use of the bench with exposed wood-like material was observed during production of Rx (b) (6) "POLYHEXAMETHYLENE HCL STERILE* 0.06% DROPS", lot 190413, on November 23, 2021.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sena G Dissmeyer, Investigator Kathleen M Jordan, Investigator	X Sena G Dissmeyer Investigator Signed By: Sena G. Dissmeyer -S Date Signed: 12-02-2021 16:22:29	12/2/2021

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OBSERVATION 3

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically, there are (b) (4) , (b) (4) , located between your unclassified hallway and your ISO 7 classified buffer rooms (b) (4) leads to your "Sterile Prep" buffer room and (b) (4) to your "Chemo Prep" buffer room. According to RTM, Owner/Compounding Specialist, production materials used in the production of sterile products, are exchanged through these (b) (4) . As they are currently designed, these (b) (4) permit unclassified air to enter the ISO 7 classified area.

Use of the (b) (4) leading to the "Sterile Prep" buffer room was observed during production of Rx (b) (6), "POLYHEXAMETHYLENE HCL STERILE* 0.06% DROPS", lot 190413, on November 23, 2021.

OBSERVATION 4

ISO 5 classified areas were not certified under dynamic conditions.

Specifically, unidirectional airflow was not verified under dynamic operational conditions representative of your aseptic processing practices. Air visualization studies ("smoke studies") performed in July of 2021, in your ISO 5 classified laminar airflow hood (LAFH) and biological safety cabinet (BSC), did not demonstrate unidirectional airflow during representative sterile processing. Review of the smoke study video revealed gloved hands moving overtop the work bench, holding one syringe tip, without the additional materials typically used in sterile production such as vials, syringes, and a beaker. For example, production of Rx (b) (6) "POLYHEXAMETHYLENE HCL STERILE* 0.06% DROPS", lot 190413, on November 23, 2021, included a (b) (4) container,

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a Polyhexamethylene (b) (4) solution container, (b) (4) , (b) (4) syringes, and a (b) (4) through with (b) (4) method mixing operations occurred.

***DATES OF INSPECTION**

11/08/2021(Mon), 11/09/2021(Tue), 11/15/2021(Mon), 11/16/2021(Tue), 11/17/2021(Wed), 11/18/2021(Thu), 11/19/2021(Fri), 11/23/2021(Tue), 12/02/2021(Thu)

X Kathleen M Jordan
Investigator
Signed By: Kathleen Jordan -S
Date Signed: 12-02-2021 16:23:01

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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."