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 [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

Sena G Dissmeyer, Investigator
Kathleen M Jordan, Investigator
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

11155 Dolfield Boulevard, Suite 117
Owings Mills, MD 21117
(410) 779-5455 Fax: (410) 779-5707
ORAPHARM1_RESPONSES@fda.hhs.gov

DATE OF INSPECTION
11/8/2021 - 12/2/2021*

PERM NUMBER
3004562873

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

FIRM NAME
Valgene Incorporated dba Cape Drugs

STREET ADDRESS
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

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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Sena G Dissmeyer, Investigator
Kathleen M Jordan, Investigator

DATE ISSUED
12/2/2021
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**FOOD AND DRUG ADMINISTRATION**

**DISTRICT ADDRESS AND PHONE NUMBER**  
11155 Dolfield Boulevard, Suite 117  
Owings Mills, MD 21117  
(410) 779-5455  
Fax: (410) 779-5707  
ORAPHARM1_RESPONSES@fda.hhs.gov

**DATE(S) OF INSPECTION**  
11/8/2021-12/2/2021

**FEIN NUMBER**  
3004562873

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

**FIRM NAME**  
Valgene Incorporated dba Cape Drugs

**STREET ADDRESS**  
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

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Sena G Dissmeyer, Investigator  
Kathleen M Jordan, Investigator |

**INSPECTIONAL OBSERVATIONS**

A Polyhexamethylene solution container, syringes, and a 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)
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."