DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772	6/8/2026-6/17/2026* FEI NUMBER 3017865039

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andrew T. Bruggeman , Director, 503A Pharmacist in Charge

FIRM NAME	STREET ADDRESS
XeCare LLC	9750 Innovation Campus Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New Albany, OH 43054-7708	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

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically,

1) Your firm routinely produces hazardous drug products on shared tablet press equipment without employing a deactivating agent as part of the cleaning process between batches, relying solely on (b) (4) From 6/3/2026 through 6/9/2026, your firm produced the following hazardous drug products sequentially on tablet press NP4-2405 with only (b) (4) cleaning performed between each product:
   a. Tadalafil 8.5mg + Enclomiphene citrate 12.5mg tablets lots DFJRJFLEQPRS and QHKTRRHEKQFE
   b. Tadalafil 8.5mg + Finasteride 1.2mg + Minoxidil 3mg + Biotin 2.5mg + Vit B12 1mg + Vit D3 0.05mg + L-Theanine 50mg Tablets lots IKTTDKQPCGUT and TIGISITHFHGD
   c. Naltrexone HCL 14mg + Topiramate 44mg Vitamin B12 1mg Tablets lots UFISFTCFFTPS and DLCQHEGLUTQE

2) Your firm routinely performs hazardous drug powder weighing and sifting operations in Room 104, your designated hazardous weighing room, under conditions that do not consistently meet the required negative air pressure specifications. Review of the Building Management System

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Logan T Williams, Investigator Kara J Wright, Investigator	Logan T Williams Investigator Signed By: J002955055 Date Signed: 06-17-2026 13:08:34 X	6/17/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	6/8/2026-6/17/2026* FEI NUMBER 3017865039

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(BMS) data for Room 104 from 5/13/2026 through 6/10/2026 revealed approximately 56 pressure differential alarm events, with excursion durations ranging from 5 minutes to a continuous all-day alarm on 6/9/2026.

During this period, your firm actively weighed, sifted, or mixed, approximately (b)(4) batches while alarm limits were exceeded. Batches weighed and sifted during this period include but are not limited to:

a. Naltrexone HCL 14mg + Topiramate 44mg + Vitamin B12 1mg Tablet lot JGSLGUJJEFSI
b. Tadalafil 8.5mg + Enclomiphene Citrate 12.5mg Tablet lot DFJRJFLEQPRS
c. Finasteride 1.2mg + Minoxidil 3mg + Vitamin B12 1mg + Biotin 2.5mg + Vitamin C 100mg + Resveratrol 20mg + Zinc Sulfate 30mg Tablet lot UQTESLQHDGIF

Your firm also actively weighed one batch of drug product, Naltrexone HCL 14mg + Topiramate 44mg + Vitamin B12 1mg Tablet lot KQUGJSJERGIP, during this period when positive pressure, 0.001" - 0.002" WC, was exhibited by Room 104 and Room 103a which should be negative pressure rooms by design, specification range (b) (4)

LTW 6/17/2026

OBSERVATION 2
Materials were exposed to lower than ISO 5 quality air.

Specifically,

On 5/16/2026, during production of Semaglutide 5mg/2mL Solution for Injection, lot CERKTLEQQQIJ, we observed, via video review, the following poor transfers of material into the ISO-5 hood resulting in the material being exposed to the ISO-7 environment.

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	Logan T Williams, Investigator Kara J Wright, Investigator	Logan T Williams Investigator Signed By: 1002930025 Date Signed: 06-17-2026 13:08:34 X	6/17/2026

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- At approximately 7:17pm the filling technician passed two inner bags of sterile tweezers into the ISO-5 hood while exposing the inner bags to the ISO-7 environment.
- At approximately 7:24 PM, 7:48 PM, and 8:02 PM, vial trays were transferred into the ISO-5 hood with the inner bag opened within the ISO-7 environment. During each transfer, the exposed vial tray was introduced into the hood with an approximate one-foot gap between the tray and the hood opening, resulting in direct exposure of the vial tray to the ISO-7 environment.

OBSERVATION 3

Use of ingredients not intended for pharmaceutical use in non-sterile drug production.

Specifically,

Your firm makes Minoxidil 1.5mg + Biotin 2.5mg chewable gummy products using (b) (4) (b) (4) water that has not been tested. This water is used in your firm's formulation of the gummy product. Untested (b) (4) water was used in the production of Minoxidil 1.5mg + Biotin 2.5mg chewable gummy lot UGDFEUSJHFGJ.

***DATES OF INSPECTION**

6/08/2026(Mon), 6/09/2026(Tue), 6/10/2026(Wed), 6/11/2026(Thu), 6/12/2026(Fri), 6/15/2026(Mon), 6/16/2026(Tue), 6/17/2026(Wed)

Kara J Wright
Investigator
Signed By: 2004338119
X Date Signed: 06-17-2026 13:09:26

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Logan T Williams, Investigator Kara J Wright, Investigator	Logan T Williams Investigator Signed By: 2002955055 Date Signed: 06-17-2026 13:08:34 X	6/17/2026

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."