

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext. 5301 Fax: (718) 662-5661 CDER-OC-OMQ-Domestic483Response@fda.hhs.gov		DATE(S) OF INSPECTION 03/16/2026-03/23/2026* FBI NUMBER 3005890568
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Manish S. Shah, President		
FIRM NAME Cerovene Inc.	STREET ADDRESS 612 Corporate Way Ste 10	
CITY, STATE, ZIP CODE, COUNTRY Valley Cottage, NY 10989-2027	TYPE ESTABLISHMENT INSPECTED Contract Drug Manufacturer	
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.		
<i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i>		
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 (Repeat) Equipment and utensils are not cleaned, maintained at appropriate intervals to prevent malfunctions contamination that would alter the safety, identity, strength, quality or purity of the drug product. Specifically, During the inspection, we observed the following equipment cleaning deficiencies for equipment identified as having been cleaned: A. On 03/16/2026, we observed (b) (4) was being stored directly on the (b) (4) floor of (b) (4) while manufacturing (b) (4) Tablets USP (b) (4) Batch # (b) (4). The (b) (4) is utilized for unloading materials from (b) (4). B. On 03/16/2026, presence of white caked residue was observed in Capsule Machine ID # (b) (4) (Non-dedicated) product contact surfaces including cavities for encapsulation and Capsule (b) (4) ID # (b) (4). The equipment is located in Room # (b) (4) (Capsule Machine Room) and was cleaned for type “(b) (4)” cleaning (Major cleaning) on (b) (4) after manufacturing (b) (4) Capsules USP, (b) (4) Batch # (b) (4) on (b) (4), and the equipment was issued a “Cleaned” status. C. On 03/18/2026, presence of unknown white powder was observed inside the validation (b) (4) locations inside (b) (4) ID # (b) (4) located inside Room # (b) (4) Block (b) (4) (non-dedicated equipment). The equipment was last used for manufacturing (b) (4) and (b) (4).		
SEE REVERSE OF THIS PAGE	Yvins Dezan, Investigator Josh Renzo N Ramilo, Investigator Yvins Dezan -S JOSH RENZO N. RAMILO -S Digitally signed by Yvins Dezan -S Date: 2026.03.23 12:56:20 -04'00' Digitally signed by JOSH RENZO N. RAMILO -S Date: 2026.03.23 12:56:42 -04'00'	
		DATE ISSUED 03/23/2026

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(b) (4) on (b) (4). A type “(b) (4)” cleaning (Major) was performed on (b) (4) (b) (4), and the equipment was issued a “Cleaned” status.

- D. On 3/18/2026, we observed the presence of white cake residue and buildup inside the (b) (4) Tablet Press Machine, ID # (b) (4) (non-dedicated equipment). The equipment was last utilized on (b) (4) to manufacture (b) (4) Tablets Batch # (b) (4). A type “(b) (4)” (Major) cleaning was performed on (b) (4) and the equipment was issued a “Cleaned” status.

OBSERVATION 2 (Repeat)

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Specifically,

- A. Per your VP of Operations, your firm does not review data, audit trails and alarm reports generated by the HMI ((b) (4)) of your non-dedicated (b) (4) Mixer (b) (4) ID# (b) (4). Operators that use this equipment have a shared (b) (4) login and password “(b) (4)” for its operation and the date in the system was displayed as “01/10/25” and 15:09:34 on 03/18/2025 at 12:30pm. Per your Vice President Operations, alarms generated from the HMI are not backed up, printed, and automatically overwritten by the system after (b) (4).
- B. On 03/16/2026, we observed (b) (4) analytical balance ID # (b) (4) located in the Analytical Balance Room is not password-protected from changing the date and time by unauthorized users. Your QC Manager (b) (6), (b) (7), (C)) was able to change the date and time from the balance without log-in credentials. The analytical balance is utilized for weighing commercial drug product samples, chemical, and reagents for mobile phase preparation in the QC Lab for commercial drug products including (b) (4) Capsules, (b) (4) Tablets.

OBSERVATION 3

Established lab control mechanisms are not followed.

Specifically,

During our lab walkthrough on 3/16/2026, we observed (b) (4) volumetric flasks in the volumetric flask cabinet, containing expired stock standards for both impurities and the active compound, along with their

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Yvins Dezan, Investigator Yvins Dezan -S Digitally signed by Yvins Dezan -S
Date: 2026.03.23 12:56:20 -0400
Josh Renzo N Ramilo, Investigator JOSH RENZO N. RAMILO -S Digitally signed by JOSH RENZO
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corresponding working standards. This cabinet contained (b) (4) stock standards, (b) (4) intermediate standard, (b) (4) diluent and (b) (4) working standards. Out of these (b) (4) flasks containing working standards, 7 flasks lacked a preparation date. I observed the following expired stock and working standards used for the testing of commercial drug products, in this cabinet:

Product	Type of Standard	Preparation Date	Expiry after preparation	Expiry determined according to
(b) (4) Tablets (b) (4), (b) (4)	Impurity working standard	July 25, 2025	(b) (4)	Method Validation MVR_(b) (4)_Related Substances_2018_95
(b) (4) Tablets (b) (4)	Stock standard for assay	January 30, 2026	(b) (4)	Method Validation MVR_(b) (4)_Assay_2018_94
	Working standard for assay	January 30, 2026		
(b) (4) (b) (4) tablets	Stock dissolution standard	January 16, 2026		Method Transfer MTR_(b) (4)_ (b) (4)_2024_36
	Stock dissolution standard	November 20, 2025		
	Working dissolution standard			
Soap (Cleaning Validation)	Intermediate standard	May 30, 2025		Method Validation MVR_Soap_Cleaning_2012_17 Method
	Working standard	September 18, 2025		

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(b) (4) API	Intermediate standard	No date	(b) (4)	Method Transfer
	Impurity (b) (4) working standard			(b) (4)
	Impurity (b) (4) working standard			(b) (4)
	Impurity (b) (4) working standard			(b) (4) content_2025_17
	Impurity (b) (4) working standard			
	Impurity (b) (4) working standard			
	Impurity (b) (4) working standard			

***DATES OF INSPECTION**

03/16/2026 (Mon), 03/17/2026 (Tue), 03/18/2026 (Wed), 03/19/2026 (Thu), 03/20/2026 (Fri), 03/23/2026 (Mon).

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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."