

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240) 402-9160 orabioinspectionalcorrespondence@fda.hhs.gov		DATE(S) OF INSPECTION 5/20/2024-5/28/2024* FEI NUMBER 3010227150			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Matthias Krieger, Managing Director					
FIRM NAME FinVector Oy		STREET ADDRESS Microkatu 1s			
CITY, STATE, ZIP CODE, COUNTRY Kuopio, North Savo, 70210 Finland		TYPE ESTABLISHMENT INSPECTED Biologics/Viral Vector			
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 Establishment of the reliability of the container and closure supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals. Specifically, your firm has not conducted at least one specific identity test and has not established the reliability of the supplier's analyses through appropriate validation of the supplier's test result at appropriate intervals for (b) (4) vial used as primary container for Adstiladrin drug product. Between (b) (4) (b) (4), your firm has shipped/distributed approximately (b) (4) Adstiladrin vials to the US market. In addition, you have not established a written procedure describing the sampling and testing of (b) (4) vial.					
OBSERVATION 2 The quality control unit lacks responsibility to approve all procedures or specifications impacting on the identity, strength, quality and purity of drug products. Specifically, your quality control unit has not established a procedure that governs the performance of visual inspection on reserve samples from representative sample lots at least once a year for evidence of deterioration.					
OBSERVATION 3 Written procedures for cleaning and maintenance fail to include maintenance and cleaning schedules.					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Gene D Arcy, Investigator - Team Biologics Lewis K Antwi, Investigator </td> <td style="width: 40%; vertical-align: top; text-align: center;"> DATE ISSUED 5/28/2024 Gene D Arcy Investigator - Team Biologics Signed By: 1300159963 Date Signed: 05-28-2024 07:53:36 </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Gene D Arcy, Investigator - Team Biologics Lewis K Antwi, Investigator	DATE ISSUED 5/28/2024 Gene D Arcy Investigator - Team Biologics Signed By: 1300159963 Date Signed: 05-28-2024 07:53:36
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Specifically, your firm has not established procedures for tracking or maintenance of the following equipment components: ○ (b) (4) ○ (b) (4) (located in (b) (4)) Your written maintenance procedures "Operation and maintenance of the gas storage and storage distribution systems in GMP3 and GMP4, SOP-(b) (4)-256" and "Maintenance of WFI Distribution System, SOP-(b) (4)-044" does not include routine inspection, replacement frequency and other maintenance criteria for (b) (4) and (b) (4) respectively. In addition, the above equipment components are currently not on preventative maintenance program.			
DRUG SUBSTANCE			
OBSERVATION 4 Your firm has not adequately validated your adherent (b) (4) regarding cell infection in that certain combinations of critical parameters have not been assessed. The Multiplicity of Infection (MOI) is used in a calculation in step (b) (4) of master batch record (b) (4) (b) (4), for determining a correct volume of virus particle concentrate. The MOI is a critical process parameter with a target of (b) (4) viral particles per cell (VP/Cell) and a range of (b) (4) VP/Cell. The Duration of Infection (DOI) pertains to the time taken from infection to harvest and has a normal/acceptable range of (b) (4) (page 157, master batch record (b) (4) (b) (4)). The DOI is a critical process parameter. Although the MOI target is 163 VP/Cell, there is no prohibition on using any other value within the range. Your firm has not validated combinations (including extremes) of MOIs and DOIs for acceptability regarding two (b) (4), which were observed in operation in building (b) (4) and include (b) (4) and (b) (4) (b) (4). (b) (4) was observed but reported undergoing an upgrade. Drug products batches			
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(currently under routine quarantine) produced from drug substances from (b) (4) instruments include: (b) (4) (b) (4)																		
OBSERVATION 5 Failure to check the reliability of Certificate of Analysis (COA) at Regular Intervals. Specifically, your firm has not established the reliability of suppliers COA through appropriate validation of the supplier's test result at appropriate intervals for the following components/excipients: <table><thead><tr><th>Specification Number</th><th>Material Name</th></tr></thead><tbody><tr><td>(b) (4)</td><td>(b) (4)</td></tr><tr><td>(b) (4)</td><td>(b) (4)</td></tr><tr><td>(b) (4)</td><td>(b) (4)</td></tr><tr><td>(b) (4)</td><td>(b) (4)</td></tr><tr><td>(b) (4)</td><td>(b) (4)</td></tr><tr><td>(b) (4)</td><td>(b) (4)</td></tr><tr><td>(b) (4)</td><td>(b) (4)</td></tr></tbody></table>			Specification Number	Material Name	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
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(b) (4)		(b) (4)	
(b) (4)		(b) (4)	

In addition, you have not established a written procedure describing the sampling and testing of the above materials.

*DATES OF INSPECTION

5/20/2024(Mon), 5/21/2024(Tue), 5/22/2024(Wed), 5/23/2024(Thu), 5/24/2024(Fri), 5/27/2024(Mon),
5/28/2024(Tue)

X Lewis K Antwi
Investigator
Signed By: 2001796124
Date Signed: 05-28-2024 07:54:18

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Gene D Arcy, Investigator - Team Biologics
Lewis K Antwi, Investigator

X

Gene D Arcy
Investigator - Team Biologics
Signed By: 1300159963
Date Signed: 05-28-2024
07:53:36

DATE ISSUED

5/28/2024

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."