

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA/CBER/OCBQ/DMPQ 10903 New Hampshire Avenue, Silver Spring, MD 20993 Attention: Carolyn Renshaw, Building 71 Room 4042 Telephone: 240.402.7343 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION September 19, 20, 21, 22, 23, 26 and 27, 2022
	FEI NUMBER 3010227150

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Tal Levy, Managing Director and Site Head

FIRM NAME Fin Vector Oy	STREET ADDRESS Microkatu 1 S
CITY, STATE AND ZIP CODE Kuopio, Finland 70210	TYPE OF ESTABLISHMENT INSPECTED Drug Substance and Drug Product Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (b) (4) OBSERVED:

Observation 1

As evidenced by the following deviations, there does not appear to be an adequate number of qualified personnel to perform and supervise the manufacture and/or processing of the drug product. Specifically, the following deviations were initiated due to operations personnel documenting the verification their own work:

Deviation 21011, initiated January 12, 2021

Deviation 22263, initiated May 16, 2022

Deviation 22306, initiated May 30, 2022

Deviation 22309, initiated May 31, 2022

Observation 2

Equipment used to support the manufacturing process is not maintained at appropriate intervals to prevent malfunctions, making the equipment unavailable for its intended use for equipment (b) (4). Specifically,

a. Between September 3, 2021 and July 4, 2022, multiple unplanned work orders were executed regarding breakdowns of (b) (4) in the (b) (4) area, room (b) (4). The Work Orders are as follows: WO-001063, WO-001755, WO-001802, WO-001886, WO-001891, WO-001948, WO-002183, WO-002887 and WO-003070.

b. Due to the breakdown of (b) (4) it could not be used for equipment (b) (4) during the following dates:

October 6-7 and 21-22, 2021

November 8-22 and 24-30, 2021

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE (b) (6), (b) (7)(C)	EMPLOYEE(S) NAME AND TITLE (Print or Type) Laura Fontan, CSO, Lead Inspector Jared Greeneaf, CSO, Inspector	DATE ISSUED 09/27/2022

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February 11-18, 2022
 May 31, 2022
 June 1 -10, and 22-30, 2022
 July 1-31, 2022
 August 1, 2022

During the breakdown periods, an alternate (b) (4) not intended for commercial drug product licensure was used.

c. The (b) (4) breakdown was related to the following deviations opened in 2022, which include:

Deviation 22042 (Occurrence date February 17, 2022)
 Deviation 22216 (Occurrence date May 3, 2022)
 Deviation 22493 (Occurrence date August 25, 2022)
 Deviation 22315 (Occurrence date June 2, 2022)

Observation 3

The Quality System procedure for deviations and incidents allows for planned deviations to document a departure from a previously approved process as stated below:

SOP-(b) (4)-008, version 16, effective September 7, 2022, states in step 5.1, "a deviation may also be raised to document planned departure from written procedure or previously approved process. For example, continued use of an equipment pending completion of periodic maintenance or open breakdown not impacting performance of the equipment."

Deviations 21457 (Occurrence date October 5, 2020) and 22315 (Occurrence date June 2, 2022) were initiated related to the continual use of the (b) (4) to (b) (4) equipment needed for the Adstiladrin manufacturing process. The (b) (4) area is a (b) (4) facility and not part of the proposed commercial operations.

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Observation 4

Procedures designed to prevent (b) (4) contamination do not include adequate (b) (4) frequency to confirm the effectiveness of the (b) (4). Specifically, (b) (4) Decontamination System (b) (4) currently has no requirements for (b) (4)

Observation 5

Equipment used to clean drug product (b) (4) is not adequately maintained. Specifically, (b) (4) was visible inside the (b) (4) used to clean the (b) (4) for the drug product Adstiladrin. Any potential impact to the product is unknown.

Observation 6

Performance Qualification Validation and documentation required for the labelling and packaging of the filled drug product are not complete. Specifically, the following equipment is not fully qualified:

- a. (b) (4)
- b. (b) (4) System including (b) (4)

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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 judgement, 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."