DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160 orabioinspectionalcorrespondence@fda.hhs.gov	5/30/2024-6/7/2024* FEI NUMBER 3003469991

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Marjaana Tapio, CEO, Site Director

FIRM NAME	STREET ADDRESS
PCAS Finland Oy	Messukentankatu 8
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Turku, Southwest Finland, 20210 Finland	API 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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Your firm has not investigated unknown (b)(4) (including one known (b)(4)) as indicated by an in-house analytical (b)(4) method.

An "in-house" (b)(4) method is indicated in SOP titled (b)(4) *Method Analysis*, (b)(4) DOC-00010295, among other tests (e.g., other in-house and API release tests), under product code (b)(4). Results of the in-house method is reported to the sponsor (product owner). The reference (b)(4) indicates unknown (b)(4) as the in-house method indicates more resolved (b)(4) vs. the official API release (b)(4) method for your firm. Many of the unknown (b)(4) have remained consistent across commercial lots but with changes in (b)(4) percentages, which include (b)(4) increases relating to process validation lots and commercial lots, and many of which have acceptable LOD (Limit of Detection) and LOQ (Limit of Quantitation) for the in-house method. However, your firm has not investigated unknown (b)(4) per SOP *Vaatimuksesta poikkeavien (OOS/OOT) laboratoriotulosten käsittely jaraportointi,* DOC-00002873 (English: Processing and reporting of non-conforming laboratory results (OOS/OOT)). In addition, one major known (b)(4) can only be seen using the in-house method. This (b)(4) is expected but has not been investigated as to whether the amount is an acceptable output of the manufacturing process. The following most recent API batches have been released and distributed: (b)(4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lewis K Antwi, Investigator Gene D Arcy, Investigator – Team Biologics	X Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 06-07-2024 06:02:05	6/7/2024

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OBSERVATION 2

Failure to maintain equipment used for the manufacturing of (b)(4) API.

Specifically, your firm has not established procedures for the maintenance of (b)(4) (equipment ID: (b)(4) and (b)(4) (equipment ID: (b)(4)) equipment used for the manufacturing of (b)(4) Active Pharmaceutical Ingredient (API). There is no written procedure for inspection, component replacement, calibration or other maintenance frequency/schedule for this equipment.

OBSERVATION 3

Your firm has not repaired and maintained manufacturing spaces & equipment in which bioburden-controlled manufacturing processes are conducted for API (b)(4)

On 05 JUN 2024, the following conditions were observed:

a)Two holes (apparently about the diameter of a U.S. quarter) were observed in an exhaust vent which is (b)(4) (Equip (b)(4) ; reported as meeting an ISO standard), and which continues as part of the air system. The (b)(4) (located in room (b)(4)) is used to conduct key bioburden-controlled steps in (b)(4) of your firm's manufacturing process (e.g., processes such as (b)(4)).

b)Regarding the condition of room (b)(4) (in which (b)(4) of manufacturing occur and in which certain steps in the (b)(4) of manufacturing occurs; and reported as meeting an ISO standard).

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i. Two room air intake vents appear to be partially blocked or positioned near cabinets such that effective air flow may be compromised.

ii. The sealant used to fill ceiling interfaces appears to be cracked and discolored.

iii. (b)(4), used to cover cracks in the floor, appears to be buckling and/or deteriorating.

***DATES OF INSPECTION**

5/30/2024(Thu), 5/31/2024(Fri), 6/03/2024(Mon), 6/04/2024(Tue), 6/05/2024(Wed), 6/06/2024(Thu), 6/07/2024(Fri)

X Gene D Arcy
Investigator - Team Biologics
Signed By: 1300159963
Date Signed: 06-07-2024 06:02:29

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lewis K Antwi, Investigator Gene D Arcy, Investigator - Team Biologics	X Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 06-07-2024 06:02:05	6/7/2024

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."