DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/DBM, 10903 New Hampshire Avenue; White Oak Building 22 Silver Spring, MD 20993 E-mail: CDER-OC-OMQ-International483Response@fda.hhs.gov	08/18,19,20, 21, and 08/22/2025
	FEI NUMBER 3003444315

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Adam Stoten, SVP Academic Partnership

FIRM NAME	STREET ADDRESS
Aptuit (Oxford) Ltd	111 Innovation Drive
CITY, STATE, ZIP CODE, COUNTRY Abingdon Oxfordshire OX144RZ United Kingdom	TYPE ESTABLISHMENT INSPECTED API and excipients 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

The responsibilities applicable to the quality unit are not fully followed.

Specifically.

Since June 2023, approximately (b) (4) batches of (b) (4) (b) (4) API were released to the market without assurance that they had safety levels of (b) (4) (b) (4) Additionally, the quality unit failed to develop a Risk Assessment of the Presence of (b) (4) in (b) (4) API.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure to of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed .

Specifically,

The quality unit failed to perform a thorough customer complaint investigation regarding (b) (4) batches of (b) (4) API that obtained (b) (4) contents above the specifications limits. The quality unit neither performed testing to the APIs to detect (b) (4) (b) (4) nor established a corrective and preventive action to avoid recurrence. These APIs were sent to the US market and other markets.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Jose M. Cayuela	Jose M. Cayuela, Investigator	08/22/2025

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OBSERVATION 3

Procedures designed to prevent microbiological contamination of products purporting to be non-sterile are not established.

Specifically,

a. The quality unit fails to ensure that the contract laboratory that performs the testing for the (b) (4) system used for the manufacture of APIs (i.e. (b) (4) (b) (4) and excipient, (b) (4) has adequate and validated test methods.

b. The quality control unit failed to ensure that the (b) (4) system used for the manufacture of APIs and excipient has safety level of (b) (4)

OBSERVATION 4

The quality system to approve contract laboratories to perform microbiological testing of (b) (4) APIs, and excipients is deficient.

Specifically,

1. The quality unit fails to ensure that the approved contract laboratory used to perform testing of APIs and excipient has the capabilities, equipment, test methods, knowledge, and reliability needed to perform the testing in an accurate and reliable way.

2. On December 11, 2024, the quality unit learned that since the year 2012, the approved contract laboratory performing the microbiological testing (i.e., Total Viable Count (TVC) and endotoxins) for the (b) (4) used for the manufacture of APIs and excipients neither has UKAS accreditation for the test requirements nor they conduct their analyses according to USP or EP standard. At the time of my inspection, the quality unit continues utilizing this deficient laboratory and continues accepting its questionable test results of (b) (4) (i.e., TVC and endotoxins) to approve and release APIs and excipients to the market. Firm's manufactures (b) (4) API intended for sterile injectable and other APIs intended for drug substances.

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OBSERVATION 5

The accuracy, sensitivity, specificity, reproducibility, and reliability of microbiological test methods has not been established.

Specifically,

The quality unit fails to ensure that the microbiological test methods (e.g., TVC, pathogens identification, and endotoxins) utilized for the release of APIs [e.g., (b) (4) (intended for drug product) (b) (4) (intended for sterile injectable) and excipient (b) (4) are validated.

OBSERVATION 6

The identity of each raw material of drug substance is not verified by conducting at least one test to verify the identity , using specific identity test.

Specifically,

The quality control unit fails to establish a specific identification test method for (b) (4) (b) (4) a raw material used for the manufacture of (b) (4) API,

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OBSERVATION 7

The amount of material taken from each container is not based upon appropriate criteria.

Specifically,

The quality unit fails to ensure that the amount of raw material taken for testing is based upon appropriate criteria such as criticality of the material, material variability, past history of the supplier, and the quantity needed for analysis.

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