DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	6/1/2026-6/3/2026
	FEI NUMBER 3014704316

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amanda L. Berd, Site Manager

FIRM NAME	STREET ADDRESS
Eurofins SF Analytical Laboratories, Inc.	215 Witmer Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Horsham, PA 19044-2212	Contract Laboratory

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 I OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review whether or not the batch has been already distributed.

Specifically,

a. Your firm's quality control (QC) staff observed dried and cracked Total Aerobic Microbial Count (TAMC) (b) (4) plates used for testing drug products and water samples on or before 05/25/2026, affecting samples plated on or before 05/20/2026. However, no deviation or investigation was initiated in response to the observation of dried and cracked (b) (4) plates utilized across TAMC testing of drug products, raw materials, customer-submitted water samples, and in-house environmental monitoring samples. Test results generated from these compromised plates were approved and released to customers.

During the walkthrough conducted on 06/01/2026 and 06/02/2026, the following dried and cracked (b) (4) plates were observed for TAMC testing across drug product and raw material samples, water samples and environmental monitoring samples for (b) (4) and (b) (4) incubation periods at storage temperatures of (b) (4) (b) (4) (TAMC) and (b) (4) (TYMC). Plates were read together with the QC staff after being taken from the incubation chamber.

Sample	Plated date	Read date	# of dried TAMC plates: storage temperature: (b) (4) °C	# of dried TYMC plates: storage temperature: (b) (4) °C
Different drug products and	05/27/2026	06/01/2026	(b) (4) lots containing (b) (4) plates including	(b) lots containing (b) plates including

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EMPLOYEE(S) SIGNATURE
Pushpa S Jayasekara, Investigator

X Pushpa S Jayasekara Investigator Signed By: Pushpa S. Jayasekara -S Date Signed: 06-03-2026 15:24:44

DATE ISSUED
6/3/2026

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raw materials from customers			duplicates	duplicates
	05/28/2026	06/01/2026	(b) (4) lots containing (b) (4) plates including duplicates	
	05/29/2026	06/02/2026	(b) (4) lots containing (b) (4) plates including duplicates	
Water from customers	05/27/2026	06/01/2026	(b) (4) lots containing (b) (4) plates including duplicates	
	05/28/2026	06/01/2026	(b) (4) lots containing (b) (4) plates including duplicates	
Inhouse Environmental monitoring samples	05/27/2026	06/01/2026	(b) (4) plates including duplicates from rooms 112, 116, 117, and 118	

The use of dried and cracked (b) (4) plates may compromise the ability of the media to support uniform microbial growth, thereby affecting the accuracy, sensitivity, and reproducibility of TAMC test results. Your firm did not assess the impact of these compromised plates on the validity of the test results prior to their release.

b. Your firm's QC staff failed to follow the Out-of-Specification (OOS) Investigation SOP. Your OOS SOP Q-SOP71879, titled "ESFA-H Out of Specification Investigation," with an effective date of 04/30/2024, requires that analysts immediately notify management of any test results that fall outside established specifications or are questionable in nature. Upon notification, management is required to initiate an OOS Investigation Record for Microbiology, Total Organic Carbon (TOC), or Conductivity testing. However, a

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review of microbial data from 03/23/2026 to 05/31/2026 revealed the following OOS results for microbial tests for which QC staff had not initiated the investigations per the SOP.

Sample description	Plate lot#	Plate read date	TAMC results (CFU)	Customer Specification limit (CFU)
EM plate-(b) (4)	(b) (4)	04/13/26	149	(b) (4)
EM plate(b) (4)		04/13/26	213	
EM plate-(b) (4)		04/13/26	254	
EM plate-(b) (4)		04/21/26	173	
(b) (4)		05/04/26	TNTC	
(b) (4)		05/04/26	TNTC	
(b) (4)		05/05/26	TNTC	

The failure to initiate OOS investigations for microbial test results in accordance with SOP Q-SOP71879 represents an issue in the firm's quality system.

OBSERVATION 2

Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically,

Laboratory records are incomplete in that not all microbial test results generated during testing are recorded in the official laboratory raw data reporting documents. Your firm's Quality Control (QC) staff failed to record all microbial test results in the official laboratory raw data reporting form, Microbiological Examination of Non-Sterile Products Analyst Results Form, as required by your firm's SOP (O-TC-MET27099). Specifically, when

two test methods were employed per USP <1231> the (b) (4) method (b) (4) and the (b) (4) method (b) (4) results from one method were omitted from the official raw data record. The following deficiencies were observed during a facility walkthrough and document review covering the period of 03/23/2026 through 06/02/2026:

a. On 06/02/2026, during the facility walkthrough, it was observed that QC staff completed Total Aerobic Microbial Count (TAMC) plate reading for water sample (customer sample description: (b) (4) using microbial plate lot# (b) (4) , employing both the (b) (4) method (b) (4) (b) (4) and the (b) (4) method (b) (4)) per USP <1231>. The official raw data reporting form recorded only the (b) (4) result from the (b) (4) method as 139 CFU/1 mL. The Too Numerous To Count (TNTC) result obtained from the (b) (4) method was not recorded in the official raw data reporting form.

b. Final data was released to the customer for water sample (customer sample description: (b) (4)) using microbial plate lot# (b) (4) . QC staff conducted testing using both the (b) (4) method (b) (4)) and the (b) (4) method (b) (4) per USP <1231>. The official raw data reporting form recorded only the (b) (4) method result of 399 CFU/10 mL. Results from the (b) (4) method (b) (4) were not recorded in the official raw data reporting form. The Certificate of Analysis (COA) released to the customer reflects only the (b) (4) result of 399 CFU/10 mL.

c. Final data was released to the customer for water sample (customer sample description: (b) (4)) using microbial plate lot# (b) (4) . QC staff conducted testing using both the (b) (4) method (b) (4)) and the (b) (4) method (b) (4)) per USP <1231>. The official raw data reporting form recorded only the (b) (4) method result of 1,300 CFU/mL. Results from the (b) (4) method were not recorded in the official raw data reporting form. The COA released to the customer reflects both Total Aerobic Microbial Count of 1,300 CFU/mL and >200 CFU/100 mL; however, the >200 CFU/100 mL result from the (b) (4) method is absent from the official raw data reporting form.

The failure to record all microbial test results from both test methods in the official laboratory raw data

reporting forms represents a significant data integrity deficiency with direct implications for product quality, patient safety, and regulatory compliance.

OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Laboratory test procedures for Total Aerobic Microbial Count (TAMC) do not ensure scientifically sound and reproducible results, in that sample homogeneity is not achieved during (b) (4) testing. For example; during a laboratory walkthrough conducted on 6/1/2026, QC microbiologist performed TAMC plate reading testing from the (b) (4) method on products/raw materials, (b) (4) (sample lot# (b) (4) and (b) (4)), (b) (4) Cream (sample lot# (b) (4)), and (b) (4) (b) (4) (sample lot# (b) (4)). Visible insoluble product particles and product lumps were observed in the TAMC plates.

The recorded results for all four lots indicated 0 CFU (no colony growth). No investigation, out-of-specification (OOS) inquiry, or documented evaluation was initiated to assess whether the presence of insoluble particulates may have interfered with microbial recovery or had masked colony growth on the (b) (4) plates.

The firm's written method suitability worksheets for TAMC testing via the (b) (4) method did not document any visible insoluble product particles or product lumps observed during the test method qualification procedure.

The firm's procedures reference and commit to following USP <61> (Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests) for TAMC testing; however, the firm is not adequately adhering to this standard in practice. USP <61> requires that sample preparations be homogeneous to ensure uniform distribution

of microorganisms across the plate, yet the firm's written procedure neither requires verification of sample homogeneity prior to plating nor defines acceptance criteria for sample appearance or particle dissolution. The observation of visible insoluble particulates and product lumps in prepared sample mixtures demonstrates that the firm's implementation of USP <61> is insufficient to meet this fundamental requirement. Failure to achieve homogeneity may result in physical obstruction of colony growth, leading to falsely low or absent microbial counts.

OBSERVATION 4

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy.

Specifically,

The firm's SOP Q-SOP26814, "Data Review and Report," effective 02/21/2026, requires that secondary verification be performed when colonies are observed and recorded during microbiological examination of non-sterile drug products. On 06/01/2026, QC Microbiologist read and recorded a Total Aerobic Microbial Count (TAMC) of 0 CFU on the results form for drug product sample, Lot # (b) (4) . Because 0 CFU was recorded, no secondary verification was initiated per the SOP's triggering criteria.

During a laboratory walkthrough conducted just after the initial plate reading on 06/01/2026, 1 CFU of colony growth was observed on the microbial plate associated with Lot #(b) (4) . The firm's SOP Q-SOP26814 does not include a procedural mechanism to trigger secondary verification when a result of 0 CFU is recorded, creating a systemic gap in which inaccurate zero-count readings may go undetected and unverified. The firm's quality control unit did not ensure that laboratory records accurately reflected the results of microbiological testing, and the established data review procedure did not provide adequate controls to detect or correct inaccurate plate readings recorded as 0 CFU.

OBSERVATION 5

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.

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Specifically,

Your firm's computerized Total Organic Carbon (TOC) instruments (b) (4), model (b) (4) SN-(b) (4) and (b) (4) Analytical, model (b) (4) Equipment ID: EQM25-M50-032359) used for water TOC testing for customers, are not operated under adequate controls to prevent unauthorized access.

During the inspection on 06/02/2026, it was observed that an analyst operating the TOC instrument holds system administrator-level access privileges. This level of access allows the user to: (1) create and delete user accounts; (2) modify audit trail functionality (minimum, moderate, and full); and (3) clear existing system audit trail information. No procedural, technical, or administrative controls were observed that would prevent the analyst from performing these functions independently and without supervisory authorization.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Pushpa S Jayasekara, Investigator	X Pushpa S Jayasekara Investigator Signed By: Pushpa S. Jayasekara -S Date Signed: 06-03-2026 15:24:44	6/3/2026

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."