DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	3/31/2025-4/4/2025
	FEI NUMBER 1047293

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Patrick J. Cashman, President

FIRM NAME	STREET ADDRESS
USAntibiotics LLC	201 Industrial Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bristol, TN 37620-5413	Drug 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:

Production System

OBSERVATION 1
Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not followed.

Specifically, you do not test every product lot for conformance to your microbiological specifications prior to release.

Your firm produces prescription (b)(4) products. Your product release specifications for all products produced include total microbial count and total yeast and mold count. However, you do not test every finished product lot for compliance to these specifications prior to release, for example, (b)(4) and (b)(4) for oral suspension, USP (b)(4) lot (b)(4) EXP (b)(4) was released to market on 6/21/2023 without testing for total microbial count or total yeast and mold count. The finished product COA does not include a result for these tests, it states that the product is certified to comply if tested. This lot has been distributed on the US Market.

LABORATORY CONTROL SYSTEM

OBSERVATION 2
Established laboratory control mechanisms are not followed.

Specifically,
Your firm invalidated out of specification (OOS) chromatography results obtained on 01/08/2025, for total (b)(4) Related Compounds ((b)(4)) during stability testing of (b)(4) and (b)(4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Gretchen M Laws, Investigator Michael Z Weigman, Investigator X Michael Z Weigman Investigator Signed By: MICHAEL Z. WEIGMAN -S Date Signed: 04-04-2025 10:22:13	4/4/2025

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(b)(4) Tablets, USP, (b)(4) Tablets, (b)(4) count, lot (b)(4) at the (b)(4) interval and (b)(4) storage condition, without a laboratory root cause identified. Repeat testing was performed on (b)(4) additional samples which met specification. Procedure APB 024.25, QC Laboratory Investigation Procedure, states that only (b)(4) repeat tests are appropriate for OOS stability samples. Resultant laboratory investigation, LI/25/0003, does not include scientific justification for performing (b)(4) retests. Additionally, procedure APB 024.25 states that an initial OOS result cannot be invalidated solely in favor of passing retest results. Per this procedure, when a laboratory root cause is not identified a follow up Plant Incident Investigation is required, which you did not perform. Lot (b)(4) was manufactured on (b)(4) and released for distribution in the US market on 11/01/2024.

Drug Supply Chain Security Act

OBSERVATION 3
Your firm failed to have systems in place to enable compliance with the verification requirements of the DSCSA.

Specifically, your firm does not have a written procedure in place that addresses handling, receiving notifications of, and reporting of illegitimate and suspect product.

X Gretchen M Laws
Investigator
Signed By: Gretchen M. Laws -S
Date Signed: 04-04-2025 10:22:42

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Gretchen M Laws, Investigator Michael Z Weigman, Investigator	X Michael Z Weigman Investigator Signed By: MICHAEL Z. WEIGMAN -S Date Signed: 04-04-2025 10:22:13	4/4/2025

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."