DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	6/8/2026-6/15/2026* FEI NUMBER 3003197096

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert Terry, Senior VP and Site Director

FIRM NAME	STREET ADDRESS
TriRx Huntsville Pharmaceutical Services, LLC	120 Vintage Dr Ne
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Huntsville, AL 35811-8216	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 I OBSERVED:

OBSERVATION 1

Complaint procedures are deficient in that they do not include provisions that allow for the review to determine if the complaints represent serious and unexpected adverse drug experiences which are required to be reported to FDA.

Specifically,
Written records of complaint investigations for multiple drug products do not include adequate findings, accurate trend assessments, or appropriate follow-up. Examples of these deficiencies were identified, but are not limited to, the following investigations:

- CC2025-0014 for (b) (4) Suspension, USP (b) (4)
- CC2024-0038 for (b) (4) Solution, USP (b) (4)
- CC2025-0067 and CC2025-0154 for (b) (4) Suspension (b) (4) and (b) (4) Suspension.
- CC2025-0002, CC2025-0028, CC2026-0022, CC2026-0048 and CC2026-0080 for (b) (4) (b) (4) Solution (b) (4)

Examples of deficiencies identified across these investigations include, but are not limited to, the following:

a. Unsupported root cause determinations.

b. Failure to test or adequately evaluate retained samples.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jeffrey T Prosterman, Investigator X Jeffrey T Prosterman Investigator Signed By: JEFFREY T. PROSTERMAN -S Date Signed: 06-15-2026 11:02:37	6/15/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	6/8/2026-6/15/2026*
	FEI NUMBER 3003197096

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Robert Terry, Senior VP and Site Director	
FIRM NAME TriRx Huntsville Pharmaceutical Services, LLC	STREET ADDRESS 120 Vintage Dr Ne
CITY, STATE, ZIP CODE, COUNTRY Huntsville, AL 35811-8216	TYPE ESTABLISHMENT INSPECTED Manufacturer

c. Failure to reference or evaluate relevant existing data.

d. Inadequate trend assessment and failure to cross-reference related complaints.

Your firm's written procedure for handling customer complaints, SOP 200-SOP-335, Customer Complaints, Version 3.0, effective 02-APR-2026, does not include a systematic step requiring an evaluation of each complaint and assessment of the severity of the adverse events, nor does it require documentation of the outcome.

OBSERVATION 2

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

The cleaning validation report: CV Report -(b) (4) VR-038-00 (T13 and FIP01) tests for Microbiology, (b) (4) and detergent. However, it did not test the active ingredient (b) (4) (b) (4). Additionally, drug products such as (b) (4) Solution USP, (b) (4) Suspension USP (b) (4) and (b) (4) Suspension (b) (4) are manufactured using the same equipment which does not have a valid cleaning validation for the active ingredient (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeffrey T Prosterman, Investigator	X Jeffrey T Prosterman Investigator Signed By: JEFFREY T. PROSTERMAN -S Date Signed: 06-15-2026 11:02:37	6/15/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	6/8/2026-6/15/2026* FEI NUMBER 3003197096

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert Terry, Senior VP and Site Director

FIRM NAME	STREET ADDRESS
TriRx Huntsville Pharmaceutical Services, LLC	120 Vintage Dr Ne
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Huntsville, AL 35811-8216	Manufacturer

OBSERVATION 3

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established.

Specifically,

The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm were not established and documented. Examples include:

a. The (b) (4) Assay Method Validation Summary Report (Protocol No. PRT-20-081.SR_001) for the (b) (4) assay method in (b) (4) fails the acceptance criteria for intermediate precision. This method validation was performed in 2020. The report was not officially approved by your Quality department until 06/09/2026. For intermediate precision, the report presents a result of 2.0% RSD for intermediate precision (b) (4) The results were found to be 5.98%, which exceeds the method's stated acceptance criterion of NMT (b) (4) The validation summary report states that the method passes all acceptance criteria, however, this conclusion is not supported by the validation data. There have been over (b) (4) units of drug products shipped that have used this method for release testing.

b. The (b) (4) method verification report PRT-22-097 (b) (4) and Related Substances Summary Report in (b) (4) (b) (4) incorrectly concludes that all acceptance criteria were met. In the report, there are two individual preparations at the (b) (4) level for Impurity E (120.4% and 121.7%) exceed the protocol's acceptance criteria: "recovery of each impurity between (b) (4) " Since 2023, there have been over (b) (4) units of drug products shipped that have used this method for release testing.

OBSERVATION 4

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeffrey T Prosterman, Investigator	X Jeffrey T Prosterman Investigator Signed By: JEFFREY T. PROSTERMAN -S Date Signed: 06-15-2026 11:02:37	6/15/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	6/8/2026-6/15/2026* FEI NUMBER 3003197096

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Robert Terry, Senior VP and Site Director	
FIRM NAME TriRx Huntsville Pharmaceutical Services, LLC	STREET ADDRESS 120 Vintage Dr Ne
CITY, STATE, ZIP CODE, COUNTRY Huntsville, AL 35811-8216	TYPE ESTABLISHMENT INSPECTED Manufacturer

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

1. The Process Performance Qualification (PPQ) for (b) (4) (b) (4) (VS-1000001710-084-00) is not adequate, as the impurity data supporting the qualification was generated using an analytical method that has not been established as accurate or specific at your facility.
2. The Process Performance validation report (VS-100000274-030-00) for (b) (4) with (b) (4) (b) (4) is not adequate because the potency data supporting the qualification was generated using an analytical method that has not been established as accurate or specific at your facility.

OBSERVATION 5

Routine calibration of electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

The weight of the product is not within the calibration range of the balance that is used for documenting fill weight of a finished drug product. The balance (ID: HSV-E-002461), used to perform fill weights on filling line (b) (4) is not calibrated for the in-process fill weight checks. For example, the gross weights (b) (4) Suspension, (b) (4), lot number (b) (4), exp. (b) (4) range from 166.7 grams to 168.8 grams with an average tare weight of (b) (4) grams. These weights were documented using balance HSV-E-002461. This balance is checked (b) (4) with a (b) (4) gram and (b) (4) gram weights. Additionally, the (b) (4) calibration is performed with (b) (4) gram, (b) (4) gram, (b) (4) gram, (b) (4) gram

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	6/8/2026-6/15/2026*
	FEI NUMBER 3003197096

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Robert Terry, Senior VP and Site Director

FIRM NAME	STREET ADDRESS
TriRx Huntsville Pharmaceutical Services, LLC	120 Vintage Dr Ne
CITY, STATE, ZIP CODE, COUNTRY Huntsville, AL 35811-8216	TYPE ESTABLISHMENT INSPECTED Manufacturer

and (b) (4) gram weights.

***DATES OF INSPECTION**

6/08/2026(Mon), 6/09/2026(Tue), 6/10/2026(Wed), 6/11/2026(Thu), 6/12/2026(Fri), 6/15/2026(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jeffrey T Prosterman, Investigator X Jeffrey T Prosterman Investigator Signed By: JEFFREY T. PROSTERMAN -S Date Signed: 06-15-2026 11:02:37	6/15/2026

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."