

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax: (303)236-3100	DATE(S) OF INSPECTION 08/17/2026-08/28/2026*
	FEI NUMBER 3015929581

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mitesh M. Gandhi, Executive Vice President

FIRM NAME Tailstorm Health, Inc	STREET ADDRESS 158 S Kyrene Rd
CITY, STATE, ZIP CODE, COUNTRY Chandler, AZ 85226-4472	TYPE ESTABLISHMENT INSPECTED outsourcing facility

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

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, (b) (4) operational/dynamic certification of the (b) (4) Vial Filling, Stoppering and Sealing Machine, ISO 5 (b) (4) Filling Line (b) (4) cleanroom suite does not represent routine production operations. For example, ISO 5 Filling Line (b) (4) was not fully assembled or in operation, and there was one cleanroom technician outside the (b) (4) during dynamic nonviable particulate (NVP) monitoring. We observed up to (b) (4) technicians inside the ISO 7 buffer room for the ISO 5 (b) (4) during filling of Lidocaine 2% Injection, 10 mL vial, batch 2608002. Records reviewed included: Project AZ-MVDT261801C-1, (b) (4) Cleanroom Testing and Certification, dated April 2026; and Project AZ-MVDT251301C-1, Cleanroom Suite Certification, dated October 2025. All sterile drugs are manufactured on ISO 5 Filling Line (b) (4). The personnel, line setup, and production operations inside the ISO 5 (b) (4) are the same for aseptically filled and (b) (4) sterilized drugs. Examples of aseptically filled drugs include Lorazepam Injection USP, 2 mg/mL, lot 2510002; and Lorazepam Injection USP, 2 mg/mL, lot 2511001.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

Autoclave

Qualification and routine monitoring of the (b) (4) equipment ID #PE001, is deficient.

- A. There is inadequate written justification to place (b) (4) in the (b) (4) of the (b) (4) as the only process verification for routine sterilization loads. The rationale for the location of the (b) (4) within the (b) (4) is inadequate.
- B. Operators do not use Biological Indicators (BIs) (b) (4) sterilization (b) (4). The approved procedures only require BIs during (b) (4) qualification of (b) (4) loads. The most recent (b) (4) qualification is documented in (b) (4). PQ.0004, Performance Qualification (b) (4) Report, (b) (4) PE001, report approved 06/19/26.
- C. Your procedures only require a (b) (4) air removal test during (b) (4) qualification of the (b) (4). Technicians do not perform (b) (4) tests before any routine (b) (4) cycles. There is inadequate written justification for the frequency of air

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removal tests.

Technicians use (b) (4) PE001 to (b) (4) sterilize finished drug products and sterilize reusable product-contact parts, (b) (4) tubing, (b) (4) , utensils, and other items used during production of all commercial sterile drugs on ISO 5 Filling Line (b) (4) Examples of drugs manufactured with product-contact equipment sterilized in PE001 and then (b) (4) sterilized in PE001 include: Ketamine 10% USP, 100 mg/mL, 5 mL, SDV, lot 2602003; Lidocaine HCl 1%/Epinephrine Bitartrate 10 mcg/mL Injection USP, 10 mL, SDV, lot 2603001; Albuterol Sulfate 0.5%, 10 mL, lot 2512002; and Bupivacaine Hydrochloride 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL vial, lot 2608001.

Media Fill

D. Operators do not verify the (b) (4) of prepared (b) (4) culture medium used in aseptic process simulation media fills on ISO 5 Filling Line (b) (4) There is inadequate assurance that the (b) (4) is suitable to validate the aseptic filling process for Lorazepam Injection. We reviewed the batch record for Media Fill, batch CHMF/26/001, completed (b) (4) , approved 06/11/26.

(b) (4)

E. Technicians do not use BIs for routine or periodic monitoring of the (b) (4) cycle used for (b) (4) of ISO 5 Filling Line (b) (4) and the ISO 7 buffer room before filling.

F. The (b) (4) surface remains folded inside the open (b) (4) pouch during the (b) (4) cycle for ISO 5 Filling Line (b) (4) and the ISO 7 buffer room. There are no BIs or (b) (4) placed inside the partially open pouches to demonstrate the (b) (4) adequately (b) (4) the (b) (4) that are exposed to the environment during installation of the (b) (4) in (b) (4)

Personnel Monitoring

G. Personnel monitoring specifications for (b) (4) hands, forearms, chest, and forehead are not scientifically justified. Your firm uses the ISO 7 microbial monitoring limits (b) (4) CFU/plate alert and (b) (4) CFU/plate action) to evaluate samples from operators that use (b) (4) to perform closed-door interventions in the ISO 5 Filling Line (b) (4) Samples collected from operators after open-door interventions are the only personnel samples held to the ISO 5 microbial limits (b) (4) CFU/plate).

OBSERVATION 3

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

(b) (4) System

A. We observed a leaking diaphragm valve after the final (b) (4) step on the (b) (4) skid used to supply (b) (4) for all sterile injectable drugs that contain (b) (4) Examples of drugs that contain (b) (4) from this system include:

- Ketamine 10% USP, 100 mg/mL, 5 mL, SDV, lot 2602003
- Lidocaine HCl 1%/Epinephrine Bitartrate 10 mcg/mL Injection USP, 10 mL, SDV, lot 2603001
- Albuterol Sulfate 0.5%, 10 mL, lot 2512002
- Bupivacaine Hydrochloride 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL vial, lot 2608001

B. There is an approximately one-foot-long (b) (4) connected to the (b) (4) for the (b) (4) on the (b) (4) System.

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(b) (4) contains a (b) (4) (b) (4) near the middle that leads to a closed (b) (4) on the (b) (4) from the (b) (4) System.

(b) (4) System

We observed numerous deficiencies with the design, use, testing, and maintenance of the ambient temperature, (b) (4) construction (b) (4) System dedicated to supply (b) (4) to the (b) (4), equipment ID #PE001, inside the Line (b) (4) Cleanroom suite. Operators use (b) (4) PE001 to sterilize all reusable product-contact parts and (b) (4) sterilize injectable drugs on ISO 5 Filling Line (b) (4) System flow: (b) (4)

- C. The (b) (4) System is not sampled or tested for conformance with any written specifications for chemical, microbiological, or physical attributes.
- D. The (b) (4) after the final (b) (4) step which was the beginning of the distribution line is closed. (b) (4) remains stagnant in the (b) (4) System, ambient temperature (b) (4) distribution line, flexible hose connection to the (b) (4) and (b) (4) tank inside the (b) (4) for more than (b) (4) when there is no production scheduled. There was no written justification for the start-up procedure for the (b) (4) System or (b) (4) PE001.
- E. The (b) (4) System includes numerous insanitary threaded connections, hose clamp connections, and (b) (4). This includes (b) (4) hose clamp connections after the final (b) (4) step.
- F. The (b) (4) System is not sanitized periodically and there is no written requirement.
- G. There was unknown brown residue throughout the inside of the (b) (4) housing for the (b) (4).
- H. The (b) (4) was closed on the approximately 8-inch section of pipe that supplies approximately 20 feet of pipe for the backup filling supply for the (b) (4) System break tank. The 8-inch section of pipe leading from the main (b) (4) flow line to the closed (b) (4) (b) (4) was functionally a (b) (4). The unused about 20 feet of (b) (4) (b) (4) (b) (4) was a (b) (4).
- I. The (b) (4) for the drain line was open. The flexible hose connected to the drain line was inserted approximately six inches down through a hole in the floor drain cover plate. Drain (b) (4) from the (b) (4) system was emptying into the drain and contacting the open drain hose for the (b) (4) System. This potentially allows (b) (4) to (b) (4) into the hose under specific conditions.

Examples of drugs manufactured with product-contact equipment sterilized in (b) (4) PE001 with (b) (4) from the (b) (4) System include: Ketamine 10% USP, 100 mg/mL, 5 mL, SDV, lot 2602003; Lidocaine HCl 1%/Epinephrine Bitartrate 10 mcg/mL Injection USP, 10 mL, SDV, lot 2603001; Albuterol Sulfate 0.5%, 10 mL, lot 2512002; and Bupivacaine Hydrochloride 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL vial, lot 2608001.

(b) (4)

There are inadequate written controls for (b) (4) (b) (4) testing and replacement frequency. Technicians use (b) (4) attached to ISO 5 Filling Line (b) (4) to produce all (b) (4) sterilized and aseptically filled drugs.

- J. There is no validation data to support the (b) (4) submersion test that production operators use to test the (b) (4) of (b) (4) after they remove them from ISO 5 Filling Line (b) (4) Operators wipe the (b) (4) with sporicidal, remove them from the (b) (4) after (b) (4) perform (b) (4) tests, (b) (4)

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sterilize the individually wrapped (b) (4) and then install them on the (b) (4) before the (b) (4) cycle for each (b) (4) sterilized or aseptically filled batch.

- K. There is no validation data to support unlimited (b) (4) sterilization cycles of (b) (4) (b) (4) before replacement. (b) (4) are not individually identified. The number of uses and sterilization cycles are not tracked.

OBSERVATION 4

Written records are not always made of investigations into unexplained discrepancies.

Specifically,

Particulate Matter

- A. Production processes, procedures, and equipment do not adequately exclude particulates and other potential contaminants from sterile injectable and oral inhalation drug product vials. I reviewed the two most recent (b) (4) reports for Trending of Visible Particle at Visual Inspection. The trend reports include results from 100% visual inspection and AQL inspection of finished sterile drug vials.
- a. PROT.GSP.0025, Visible Particle Trending August-Dec 2025, approved 02/03/26, documents personnel found visible particulates in multiple vials from all (b) (4) batches manufactured and inspected during the review period. The number of vials rejected for particulate matter ranged from (b) (4) (0.03%) to (b) (4) (0.46%) vials in batches that were released.
 - b. PROT.GSP.0035, Visible Particle Trending January 2026-June 2026, approved 08/18/26, documents personnel found visible particulates in at least one vial from all (b) (4) batches manufactured and inspected during the review period. The number of vials rejected for particulate matter ranged from (b) (4) (<0.01%) to (b) (4) (0.16%) vials.
- B. There is no written investigation of how extrinsic controlled particulates such as non-shedding cleanroom wipes, cleanroom (b) (4), and goggles material routinely enter vials during filling.
- C. There is inadequate scientific justification for the (b) (4) Reject Acceptance Rate Limit for critical defects per batch.

Balances

- D. Dispensing room Balance PE026 was found out-of-tolerance at the (b) (4) and (b) (4) weights during the 10/08/25 calibration. Balance PE026 was found out-of-tolerance at the (b) (4) weight during the 04/15/25 calibration. There was no investigation documented.
- E. Dispensing room Balance PE027 was found out-of-tolerance at the (b) (4) and (b) (4) weights during the 10/08/25 calibration. Balance PE027 was found out-of-tolerance at the (b) (4), and (b) (4) weights during the 04/15/25 calibration. There was no investigation documented.

Warehousing

- F. The (b) (4) Environmental Monitoring Trend Report for the Raw Material (b) (4) storage area (May 1-31, 2026) documents the temperature readings from sensors (b) (4) and (b) (4) exceeded the High Warning Limit of (b) (4) on multiple occasions throughout the month of May 2026. Maximum temperature readings on both sensors approached or reached the High Alarm Limit of (b) (4) during the same period. Quality management stated they notified the engineering department but did not document the excursion or initiate an investigation. Your firm does not have an SOP that addresses maintaining adequate storage

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conditions, and temperature controls, for raw materials and finished goods stored in the warehouse with instructions on documenting and investigating high warning or high alarm temperature limits excursions.

OBSERVATION 5

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

Specifically,
Growth Media

- A. QC microbiology personnel use Standard Methods (b) (4) (Plate Count (b) (4) for all (b) (4) bioburden samples. There is inadequate justification to use this high (b) (4) (b) (4) instead of (b) (4) designed to recover microorganisms from low (b) (4) (b) (4) systems. Growth promotion on the manufacturer COA for Plate Count (b) (4) only lists *Staphylococcus aureus*, *Escherichia coli*, and *Enterococcus faecalis*. It does not include waterborne pathogenic microorganisms of interest such as *B. cepacia* or *P. aeruginosa* that are known to colonize high purity (b) (4) systems.
- B. The firm accepts Plate Count (b) (4) plates based on manufacturer COA and does not perform growth promotion before use.

Nitrogen

Your firm uses nitrogen for pre-gassing vials and blanketing drug product solution in all lots of Lidocaine/Epinephrine Injection, Bupivacaine/Epinephrine Injection, and Lorazepam Injection. We observed multiple apparent deficiencies related to nitrogen.

- C. There was inadequate written justification to confirm that (b) (4) testing of nitrogen generated in-house ensured the nitrogen met all applicable standards each time it was used as a product-contact gas in sterile injectable and oral inhalation drugs. Drugs that require a nitrogen overlay include all lots of Lidocaine/Epinephrine Injection, Bupivacaine/Epinephrine Injection, and Lorazepam Injection. Examples of drugs manufactured with nitrogen generated in-house are Lidocaine HCl 1%/Epinephrine Bitartrate 10 mcg/mL Injection USP, 10 mL, SDV, lot 2603001; and Lorazepam Injection USP, 2 mg/mL, lot 2510002.
- D. Manufacturing personnel do not (b) (4) test the (b) (4) attached to ISO 5 Filling Line (b) (4). There is no scientific justification for the (b) (4) replacement interval for this point-of-use nitrogen (b) (4).
- E. The firm did not conduct ID tests or any other analyses on Ultra High Purity (UHP) Nitrogen, lot (b) (4), that was accepted based on supplier COA. This is a product-contact gas used during production of Bupivacaine Hydrochloride 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL vials, lot 2608001.
- F. Operators confirmed the (b) (4) of the (b) (4) they attach to the connection point for UHP Nitrogen cylinders in February 2026. Engineering technicians remove the (b) (4) when not in-use and install it when requested by production personnel. Technicians used the (b) (4) in August 2026 without performing a (b) (4) test. There is no written justification for the (b) (4) test interval. Operators (b) (4) gas from UHP Nitrogen cylinder, lot (b) (4) (b) (4), during production of Bupivacaine Hydrochloride 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL vials, lot 2608001.

Ethylene Glycol and Diethylene Glycol Testing

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G. Your firm did not perform all specific identity tests for Propylene Glycol, lot (b) (4) and Polyethylene Glycol 400, lot (b) (4). Also, your SOP titled (b) (4) LAB.0025-Sample Pooling Strategy for Diethylene Glycol and Ethylene Glycol (DEG/EG), effective 21 Oct 2025, instructs personnel to pool (b) (4) for testing of high-risk drug components. These high-risk components were used in the manufacturing of Lorazepam Injection USP, 2 mg/mL, lot 2510001 (first distribution 12/02/25), lot 2510002 (first distribution 12/01/25), and 2511001 (first distribution 05/11/26).

***DATES OF INSPECTION**

8/17/2026(Mon), 8/18/2026(Tue), 8/19/2026(Wed), 8/20/2026(Thu), 8/21/2026(Fri), 8/24/2026(Mon), 8/25/2026(Tue), 8/26/2026(Wed), 8/27/2026(Thu), 8/28/2026(Fri)

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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."