DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	5/14/2025-5/23/2025* FEI NUMBER 3015929581

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mitesh M. Gandhi, VP of Operations and Finance

FIRM NAME	STREET ADDRESS
Tailstorm Health, Inc. dba Medivant Healthcare	158 S Kyrene Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chandler, AZ 85226-4472	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
The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, your firm's batch records document significant environmental monitoring excursions during filling of sterile drugs.

A) Nonviable particulate counter (NVPC) data for five of six lots we reviewed of the (b)(4) total lots that were manufactured in 2025 using the new ISO 5 (b) (4) filling line indicate numerous action limit results occurred during filling, but your quality unit did not document a thorough investigation. For example, the following five batches were released and the first four listed were distributed:

- Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot (b) (4) had approximately 73 action limit results for (b) (4) particles and approximately 104 action limit results for (b) (4) particles. The maximum result for (b) (4) was 39,258 particles/m^3 and the maximum result for (b) (4) was 1,237 particles/m^3.
- Ketamine 1% 10 mg/mL, 5 mL (SDV), lot (b) (4) had approximately 1 action limit result for (b) (4) particles and approximately 3 action limit results for (b) (4) particles. The maximum result for (b) (4) was 31,731 particles/m^3 and the maximum result for (b) (4) was 35 particles/m^3.
- Ketamine 10% 100 mg/mL, 5 mL (MDV), lot (b) (4) had approximately eight action limit results for (b) (4) particles and approximately 14 action limit results for (b) (4) particles. The maximum result for (b) (4) was 11,661 particles/m^3 and the maximum result for (b) (4) was 389 particles/m^3.
- Lidocaine HCl 1%/Epinephrine Bitartrate 10 mcg/mL, 10 mL, lot (b) (4) had approximately 17 action limit results for (b) (4) particles and approximately 160 action limit results for (b) (4) particles. The maximum result for (b)(4) was 47,752 particles/m^3 and the maximum result for (b) (4) was 8,021 particles/m^3.
- Bupivacaine HCl Injection USP 0.25%, 10 mL, lot (b) (4) had approximately 21 action limit results for (b) (4) particles and approximately 38 action limit results for (b) (4) particles. The maximum result for (b) (4) was 154,594 particles/m^3 and the maximum result for (b) (4) was 47,526 particles/m^3.

B) Batch records for the first (b)(4) sterile lots manufactured in 2025 using the new ISO 5 (b) (4) filling line document NVPC alert and action limits in the software were set above the limits allowed per ISO guidelines and in the approved procedure SOP.CQC.0068, Environmental Monitoring Program. Your firm discovered this error in about April 2025 but did not conduct a thorough investigation per the Assessment of Non-Viable Particle Count Limit impact assessment approved 05/05/25. We reviewed six of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
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these lots and each experienced multiple excursions beyond the ISO limits for ISO 5 cleanrooms and some had excursions beyond the default limits detailed below. For example, during filling of Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot (b) (4) the (b) (4) particulate limit was set to (b) (4) and a result of 39,258 particles/m3 at the filling station did not trigger an action limit result or initiate an auto-stop on the line so filling continued through this excursion and many others beyond ISO 5 limits.

The default limits used during filling:

- Alert limit for (b) (4) particles at the (b) (4) Table was (b) (4)
- Action limit for (b) (4) particles at the (b) (4) Table was (b) (4)
- Alert limit for (b) (4) particles at the (b) (4) Table was (b) (4)
- Action limit for (b) (4) particles at the (b) (4) Table was (b) (4)
- Alert limit for (b) (4) particles at the Filling Station was (b) (4)
- Action limit for (b) (4) particles at the Filling Station was (b) (4)
- Alert limit for (b) (4) particles at the Filling Station was (b) (4)
- Action limit for (b) (4) particles at the Filling Station was (b) (4)

C) Your approved procedures do not require production technicians or quality personnel take any specific remedial actions, reject vials present on the line during the inspection, or open a quality investigation in response to NVPC action limit results during filling. Examples of batches with no investigation for NVPC action limit excursions include lot (b) (4) lot (b) (4) lot (b) (4) lot (b) (4) lot (b) (4) and lot (b) (4)

OBSERVATION 2
There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

(This is a repeat observation.)
Specifically, OOS investigations did not always contain complete written justification to support the root cause and conclusions, and investigations were not always expanded to additional lots when implicated by the root cause.

A) Investigations OOS.23.015 (lot (b) (4) OOS.24.001 (lot (b) (4) and OOS.23.016 (lot (b) (4) identified sample handling and preparation at your contract laboratory as the probable root cause for OOS liquid particle count results in finished drug lots but did not include specific actions by analysts that might have caused the OOS. The contract laboratory investigation did not find any laboratory errors. There was no thorough explanation of the discrepancy between your investigation and your contract laboratory's investigation. There was no record of remedial action at your contract laboratory to prevent reoccurrence of the unspecified root cause. Your firm re-tested these lots and then released and distributed them without identifying the source of the particles found in your drug product.

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B) Investigations OOS.24.003 (stability lot (b) (4)), OOS.24.004 (stability lot (b) (4)), and OOS.23.005 (lots (b) (4) and (b) (4)) document multiple bupivacaine assay OOS results for Bupivacaine HCl/Epinephrine Bitartrate injection. Bupivacaine assay was low for (b) (4) real-time stability sample, high for (b) (4) real-time stability sample, and high for both engineering lots. Your firm determined a weighing or dilution error was the root cause, because the ratio between the standard and sample solution was wider for the OOS lots than passing lots tested at the same time. HPLC system suitability passed, and the laboratory investigation performed by your contract lab did not find any errors. There is no specification or limit for this ratio, and it is not reviewed unless there is a problem with the initial result. Your firm did not expand the investigation to all other lots or even though the root cause identified appears to implicate all assays for this product.

OBSERVATION 3

Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release.

(This is a repeat observation.)

Specifically, we observed multiple deficiencies when we examined your firm's visual inspection, AQL, and particle identification procedures, processes, and executed records.

A) Your firm did not determine the identity, source, and route of contamination for particles and fibers observed inside sterile finished drug vials during 100% visual inspection and AQL performed (b) (4) for lots we examined. The lots met acceptance criteria for VI and AQL and were released with no additional investigation. For example,

- Inspectors identified 83 units with particles and 16 units with fibers during 100% visual inspection of Sterile Water for Injection, USP 10 mL, lot (b) (4)
- Inspectors identified 21 units with particles and eight units with fibers during 100% visual inspection of Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot (b) (4)
- Inspectors identified five units with particles and four units with fibers during 100% visual inspection of Ketamine 1% 10 mg/mL, 5 mL (SDV), lot (b) (4) QA found one additional white fiber during AQL.
- Inspectors identified four units with particles and three units with fibers during 100% visual inspection of Ketamine 10% 100 mg/mL, 5 mL (MDV), lot (b) (4) QA found one additional white particle during AQL.
- Inspectors identified 2 units with particles and 6 units with fibers during 100% visual inspection of Lidocaine HCl 1%/Epinephrine Bitartrate 10 mcg/mL, 10 mL, lot (b) (4) QA found one additional white particle and one additional fiber during AQL.
- Inspectors identified six units with particles and three units with fibers during 100% visual inspection of Bupivacaine HCl Injection USP 0.25%, 10 mL, lot (b) (4)

B) QA inspectors compare rejected defect vials from 100% visual inspection that contain particulates and fibers to the defect gallery.

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Your current procedures are deficient because they require the QA inspector to visually determine if the particle or fiber is known or unknown and then send the vial for additional identification. There was inadequate explanation how the QA inspector can visually distinguish the composition of similar particles when the description in the defect gallery is a general description such as "black particle". For example, multiple black particles or multiple white fibers will appear similar but might be different materials when examined under microscopy, FTIR, or other identification method. We also noted the procedure applies to defect vials from 100% visual inspection but does not require QA inspectors to compare particles found during AQL to the defect gallery.

C) There is inadequate written justification to classify particulates and fibers found in (b) (4) injectable drugs as major defects instead of critical defects. Critical defects have a lower defect limit.

D) You do not have adequate written justification for not identifying all particles and fibers observed during 100% visual inspection and AQL.

OBSERVATION 4
Routine inspection and checking of equipment is not performed according to a written program designed to assure proper performance.

Specifically, we observed the (b) (4) unit on your (b) (4) (b) (4) leaking and creating a puddle on the floor on 05/14/25. There were no records available to determine how long this leak was present. Your firm uses (b) (4) to produce approximately (b) (4) different (b) (4) injectable drugs. Examples of lots produced with (b) (4) include: Sterile Water for Injection, USP 10 mL, lot (b) (4) Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot (b) (4) Ketamine 10% 100 mg/mL, 5 mL (MDV), lot (b) (4) and Bupivacaine HCl Injection USP 0.25%, 10 mL, lot (b) (4)

OBSERVATION 5
Buildings used in the manufacturing, processing and packing of a drug product are not maintained in a good state of repair.

Specifically, we observed maintenance deficiencies with the cleanrooms production technicians use to manufacture all (b) (4) injectable drugs including: Sterile Water for Injection, USP 10 mL, lot (b) (4) Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot (b) (4) Ketamine 10% 100 mg/mL, 5 mL (MDV), lot (b) (4) and Bupivacaine HCl Injection USP 0.25%, 10 mL, lot (b) (4)

A) We observed multiple pieces of apparent (b) (4) tape under the conveyor belt and on the wall surrounding the outlet from the sealing and capping station of the ISO 5 (b) (4) filling line into the ISO 7 (b) (4) room. There was no written explanation of why the tape was present or how long it was present.

B) We observed a missing electrical outlet cover in the ISO 7 (b) (4) room with an apparent black substance surrounding the entire outlet. There was no written explanation of how long the outlet cover was missing or the identity of the black substance.

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***DATES OF INSPECTION**
5/14/2025(Wed), 5/15/2025(Thu), 5/16/2025(Fri), 5/19/2025(Mon), 5/20/2025(Tue), 5/21/2025(Wed), 5/22/2025(Thu), 5/23/2025(Fri)

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EMPLOYEE(S) SIGNATURE
Nicholas L Hunt, Investigator
Ronda R Loyd Jones, Investigator

X Nicholas L Hunt Investigator Signed By: Nicholas L. Hunt -S Date Signed: 05-23-2025 14:58:16

DATE ISSUED
5/23/2025

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."