

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

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| 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 7/7/2021-7/21/2021* |
| | FEI NUMBER 3015929581 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andrew E. Stasiak, Director Quality Assurance

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| FIRM NAME TAILSTORM HEALTH INC | STREET ADDRESS 158 S Kyrene Rd |
| CITY, STATE, ZIP CODE, COUNTRY Chandler, AZ 85226 | TYPE ESTABLISHMENT INSPECTED Outsourcer 503B |

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

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

For example:

a) Visual inspection results of filled vials were found to contain extraneous unidentified visible materials (particles and fibers) during 100% visual inspection processes, but no investigation was opened to identify the foreign materials, determine root cause as to how visible substances are found in a drug that is (b) (4) and containerized/filled in a HEPA filtered (ISO 5) environment, and prevent recurrence. For example, the following lots were found with some vials containing foreign substances:

- i) Ketamine HCL Injection Lot (b) (4) found 5 vials with white particles and 3 vials with glass particles in December 2020.
- ii) Calcium Chloride Injection Lot (b) (4) found 49 vials containing glass particles, 143 vials with white particles, and 33 vials with fibers in November 2020.
- iii) Lidocaine HCL Injection Lot (b) (4) found 3 vials with fibers and one vial with a particle in March 2021.

b) An OOS investigation (OOS 21003, January 2021 Ketamine HCL Inj Lot (b) (4)) concerning the analysis of Ketamine HCL Injection for sterility found a failing result but did not fully pursue root cause to determine adequacy of testing procedures. "Analyst believes that colony formation is likely due to inadvertent contamination during sample preparation" but what precisely went wrong with the method was not investigated and no corrective/preventative actions were implemented. An additional sample preparation was

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analyzed and found meeting specifications. Results from the retest were used as the final analytical result with no data supporting laboratory errors identified in the first test and without scientific basis for invalidating initial OOS results in favor of passing retest results. For example, (b) (4) vials of Ketamine HCL Inj for Lot (b) (4) were shipped in June 2021 to a customer in (b) (4) and in May 2021 (b) (4) vials were shipped to a customer in (b) (4).

c) An OOS investigation (OOS 21008, March 2021 Calcium Chloride Injection Lot (b) (4)) concerning the analysis of (b) (4) stability of Calcium Chloride Injection for sterility found a failing result but did not fully pursue root cause to determine adequacy of testing procedures. Growth was found in both (b) (4) and (b) (4) "The Analyst believes that contamination may have occurred during sample preparation, since there was no microbial growth observed at earlier time points..." but what precisely went wrong with the method was not investigated and no corrective/preventative actions were implemented. An additional sample preparation was analyzed and found meeting specifications. Results from the retest were used as the final analytical result with no data supporting laboratory errors identified in the first test and without scientific basis for invalidating initial OOS results in favor of passing retest results.

d) An OOS investigation (OOS 21005, February 2021 Lidocaine HCL Injection Lot (b) (4) and Calcium Chloride Injection Lot (b) (4)) concerning the analysis of (b) (4) stability of Lidocaine Injection and (b) (4) stability of Calcium Chloride Injection for sterility found failing results but did not fully pursue root cause to determine adequacy of testing procedures. "The Analyst believes that contamination may have occurred during sample preparation, since none of the other previous time points for either product had shown any microbial growth." What precisely went wrong with the method was not investigated and no corrective/preventative actions were implemented. Additional sample preparations were analyzed and found meeting specifications. Results from the retests were used as the final analytical result with no data supporting laboratory errors identified in the first tests and without scientific basis for invalidating initial OOS results in favor of passing retest results. For example, (b) (4) vials of Lidocaine HCL Inj Lot (b) (4) were shipped from your facility to a customer in (b) (4)

e) An OOS investigation (OOS 20022, November 2020 Calcium Chloride Injection Lot (b) (4)) concerning the analysis of Calcium Chloride Injection for sterility found failing results but did not fully pursue root cause to determine adequacy of testing procedures. "The Analyst believes that this is likely due to contamination during

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the sample preparation process, since historically, none of the previous batches had shown any microbial growth." What precisely went wrong with the method was not investigated and no corrective/preventative actions were implemented. Additional sample preparations were analyzed and found meeting specifications. Results from the retests were used as the final analytical result with no data supporting laboratory errors identified in the first test and without scientific basis for invalidating initial OOS results in favor of passing retest results.

OBSERVATION 2

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.

a) When there is no scientific basis found for invalidating initial out-of-specification (OOS) test results and no assignable cause for the OOS is determined, procedures (SOP.CH.0002 Investigating Out-of-Specification Test Results) allow re-testing, which permits reporting (b) (4) additional analyses that meet specifications, averaged, as the final result. Procedures in section 4.5.7.1.4. read in part, "If the investigation cannot determine any readily identifiable sources of analyst error and cannot invalidate the original result the following retest methodology should be implemented: " And continues in section 4.5.7.1.4.4. "Based on this analysis, the original sample can either be confirmed as OOS or rejected." [See Observation 1 concerning retesting]

b) Cleaning verification performed to provide evidence that the cleaning methods utilized are effective in removing drug residue in preventing cross contamination from shared equipment used in production of preparations such as Ketamine HCL Injection, Lidocaine HCL Injection and Calcium Chloride Injection incorporated (b) (4) sampling followed by analysis. Your firm does not have data, such as (b) (4) (b) (4) recovery studies, to show that residues on surfaces sampled by (b) (4) are recovered, and at what level, to fully verify effective cleaning. Shared equipment includes a (b) (4) formulation tank.

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c) Container closure integrity for drug preparations, such as Ketamine HCL, Lidocaine HCL and Calcium Chloride Injection, packaged in (b) (4) ml stoppered glass vials, is not verified to show containers are appropriate for maintaining sterility and quality of the products.

d) Software validation for HPLC is not conducted (b) (4) used for assay analysis of Lidocaine HCL Injection) to ensure the computer system consistently fulfills intended purposes and produces accurate and reliable results. For example, (b) (4) vials of Lidocaine HCL Inj Lot (b) (4) were shipped in May 2021 to customers in (b) (4)

e) (b) (4) produced at your firm, used as an ingredient in Calcium Chloride, Ketamine HCL and Lidocaine HCL Injections, is not tested for bacteria, nor are specifications established by your firm for microbial requirements of (b) (4) ((b) (4) are included in your testing program).

f) Method suitability for the sterility method used (in the presence of drugs such as Lidocaine, Ketamine and Calcium Chloride) was not performed. Sterility testing is conducted on finished drug preparations, labeled as sterile, but the analytical method (SOP.MC.008 Microbiological Testing of Pharmaceutical Products by (b) (4) Method) used is not verified for suitability in the recovery and detection of potential microbes in the presence of drug products prepared at your facility.

OBSERVATION 3

Equipment for adequate control over micro-organisms is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

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a) (b) (4) media plates used for detecting microbes (in ISO 5 RABS area during filling) utilizing passive air sampling methods (settle plates) do not contain neutralizing agents to ensure detection and growth of microbes in the presence of disinfecting agents in the filling room.

b) Procedures for use of settle plates in viable air monitoring and control in the RABS filling area do not include limits for duration of exposure (e.g., less than (b) (4) to avoid drying) to ensure that media used is growth supporting. Plates may get exposed during filling up to (b) (4) without replacement.

OBSERVATION 4

The container labels of your outsourcing facility's drug products are deficient.

The containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B). Specifically, the container from which the individual units of the drug are removed for dispensing or for administration shall include:

a. Route of administration

Examples of drug product containers that do not contain this information:

- Lidocaine 4% (200mg/5mL) 5mL HCl injection, Lidocaine 1% (100mg/mL) 10mL HCl injection, and Lidocaine 2% (200mg/10mL) 10mL HCl injection

***DATES OF INSPECTION**

7/07/2021(Wed), 7/08/2021(Thu), 7/09/2021(Fri), 7/12/2021(Mon), 7/13/2021(Tue), 7/15/2021(Thu), 7/19/2021(Mon), 7/21/2021(Wed)

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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."