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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1201 Main Street, Suite 7200<br>Dallas, TX 75202<br>(214)253-5200 Fax:(214)253-5314 | 2/2/2026-2/12/2026*<br>FEI NUMBER<br>3005641023 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul M. Costales, Director of Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Enemeez LLC | 1406 W Victory Ln |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Phoenix, AZ 85027-1309 | 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

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

Your quality unit failed to provide adequate quality oversight, based on the numerous cGMP deficiencies found during the inspection. Examples of this include, but may not be limited to:

1. You failed to perform an adequate bulk hold time study for product held in the manufacturing tank and (b) (4) before being packaged. The hold time report documented an elapsed time from when a batch is blended until it is packaged in a tube. There is no documentation of a hold study of the product held in (b) (4) before it is packaged.

2. Your firm did not have documentation of a method validation or method verification performed by the contract laboratory of its modified version equivalency to USP <61> and USP <62>.

3. Since October 2024, there have been approximately (b) (4) batches that have been shipped from your facility before they were released by the quality unit. This practice deviates from section 6.6.2.1 of your SOP QMS-213, Material Control, which requires quality release prior to shipment.

## OBSERVATION 2

| 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: 02-12-2026 09:14:37 | 2/12/2026 |

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

Specifically,

On 12/20/2024, the QA Director was notified by the contract laboratory of an OOS result of "too numerous to count" (TNTC) for total plate count of a sample from a cleaning validation (Document number CVNM702-SR) for the (b) (4) ((b) (4)) filling system. The QA Director wrote a deviation in the report describing the OOS, but the lab OOS investigation was not included in the deviation. No further investigation was conducted by QA, and the report was signed off on 08/07/2025.

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**OBSERVATION 3**

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically,

Finished product tests for the active ingredient are sampled from the manufacturing tank rather than from the final finished product package for the following products:

1. (b) (4)
2. (b) (4)
3. (b) (4)
4. (b) (4)

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|---|---|
| Paul M. Costales, Director of Operations | |
| FIRM NAME<br>Enemeez LLC | STREET ADDRESS<br>1406 W Victory Ln |
| CITY, STATE, ZIP CODE, COUNTRY<br>Phoenix, AZ 85027-1309 | TYPE ESTABLISHMENT INSPECTED<br>Manufacturer |

5. (b) (4)

**OBSERVATION 4**

Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

Your firm failed to perform all identification tests required by the USP monograph for incoming raw materials. Since January 2024, your firm received (b) (4) lots of (b) (4) and (b) (4) lots of (b) (4), USP, on which full identification testing was not performed. These raw materials were used in the production of the OTC drug products (b) (4) and (b) (4) which were manufactured from January 2024 through January 2026."

**OBSERVATION 5**

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,

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Your firm's cleaning validation for the manufacturing tank, which is used to make the (b) (4) different versions of your OTC (b) (4) products does did not include testing for residual traces of the non-rinse cleaning solution.

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***DATES OF INSPECTION**
2/02/2026(Mon), 2/03/2026(Tue), 2/04/2026(Wed), 2/05/2026(Thu), 2/06/2026(Fri), 2/12/2026(Thu)

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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."