DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New Jersey District Office 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 Ph: (973)331-4900 Industry Information: www.fda.gov/oc/industry	01/13/2026-01/27/2026* FEI NUMBER 3024366553
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Mr. Keyur Patel, Interim Production Supervisor	
TO: FIRM NAME Neeyaan LLC	STREET ADDRESS 4 Corporate Dr
CITY, STATE, ZIP CODE, COUNTRY Cranbury, NJ 08512	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

DRUG PRODUCTS

LABORATORY CONTROL SYSTEM

OBSERVATION 1

Laboratory records are deficient in that they do not include a complete record of all data obtained during testing. Specifically,

The original raw data from the firm's own testing and Certificate of Analysis (COA) from the third-party testing laboratory that performed the finished product testing for OTC Drug Product (b) (4), USP ((b) (4) Tablet) Lot # (b) (4) could not be identified or provided during the inspection. Your firm personnel provided two different Certificates of Analysis (COAs), on 01/13/2026 and 01/21/2026, transcribed on your firm's template, that contained differing analytical results for the same lot of (b) (4) (Lot #(b) (4)). Refer to the table below for the results noted in the two COAs:

	Results on COA (Date of Analysis: 04/15/2025) (Provided on 01/13/2026)	Results on COA (Date of Analysis: 05/28/2025) (Provided on 01/21/2026)
Tablet Thickness in Inches	0.198"	0.190"
Hardness Kp	12.0 Kp	12 Kp
Friability	0.2%	0.19%
Final Weight	1047.0 mg	1039.6 mg
Disintegration	2.2 min	1.6 min
Active Ingredient (b) (4) USP	104.7% ((b) (4))	100.0% ((b) (4))

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	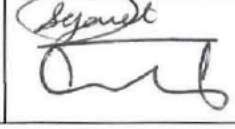	Janet A. Rajan, Investigator Charlotte P. Chang, Investigator	01/27/2026

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OBSERVATION 2

There is no written testing program designed to assess the stability characteristics of drug products. Specifically,

No stability studies have been conducted to support the (b) (4) expiration date applied for the OTC drug product (b) (4), USP ((b) (4) Tablet) in accordance with SOP-80 "Stability Studies". For example, (b) (4), USP ((b) (4) Tablet) Lot # (b) (4) and Lot # (b) (4), manufactured in (b) (4) and (b) (4), respectively, were assigned an expiration date of (b) (4) and (b) (4), respectively, without scientific rationale. Additionally, the firm has not placed representative batches on annual stability for (b) (4), USP ((b) (4) Tablet) manufactured in (b) (4).

OBSERVATION 3

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

No method validation, verification, or suitability studies have been performed for test methods including, but not limited to, the following methods used for release testing of OTC drug product (b) (4) USP ((b) (4) Tablet):

A) Assay per USP Monograph
B) Total Aerobic Microbial Count (TAMC) performed according to USP <61>
C) Total Combined Yeasts and Mold Counts (TYMC) performed according to USP <61>
D) Tests for specified microorganisms performed according to USP <62> for the detection of *Salmonella* species, *Escherichia coli*, *Staphylococcus aureus*.
E) Heavy Metal Testing for (b) (4) per USP <233> Elemental Impurities

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QUALITY SYSTEM

OBSERVATION 4

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed. Specifically,

A) A deviation was not initiated, in accordance with SOP-50 "Deviations", on 01/14/2026 when compression operations for (b) (4) Lot #(b) (4) tablets on the (b) (4) Tooling Tablet Press ((b) (4)) (Compression Room #(b) (4) were halted, per the Interim Production Supervisor, supposedly due to tablet sticking and breaking issues. The compression operation was not accompanied with a batch production record and there was no documentation indicating that sticking or breaking issues occurred during compression of this batch. Additionally, no formal investigation was initiated to assess the potential impact on product quality or to identify root causes of the sticking and breaking.

B) Annual Product Quality Reviews (PQRs) have not been performed in accordance with section 5.2 of SOP-47 "Product Quality Review," for drug products, including, but not limited to, the following manufactured and packaged products in 2025:

a. (b) (4) tablets
b. (b) (4) tablets
c. (b) (4) tablets
d. (b) (4) tablets

C) Shipping documents for OTC drug product (b) (4) , USP ((b) (4) tablet) Lot # (b) (4) and Lot # (b) (4) were not retained as required by Section 5.14 and Annexure 41B of SOP-41 "Finish Product Release & Distribution" which states that all documentation related to finished product release for distribution should be kept and stored by the QA department for at least one year after the expiration of the related batch.

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D) Batch production records for OTC drug products manufactured and/or packaged by your firm, including (b) (4) , USP ((b) (4) Tablet) Lot #(b) (4) and Lot #(b) (4) , (b) (4) tablet Lot #(b) (4), (b) (4) tablet Lot #(b) (4), and (b) (4) tablet Lot #(b) (4) , are deficient in that they are incomplete, lack second person verification of operations, do not include yield calculations, and have not been reviewed and approved by the Quality Unit.

E) Your firm has no procedure for assigning lot numbers and/or manufacturing codes for drug products manufactured and/or packaged at the firm.

OBSERVATION 5

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration. Specifically,

Retain samples for OTC drug products manufactured and/or packaged by your firm are not inspected annually for evidence of deterioration and SOP-46 "Retain Samples" does not include requirements for conducting annual inspections. In addition, the firm does not maintain a Retain Sample Logbook or a record of the inventory of retain samples as required by section 5.10 of SOP-46. Furthermore, section 5.11 of SOP-46 requires that retain samples be stored in a designated, secure, and climate-controlled storage area; however, on 01/21/2026, we observed the retain sample of (b) (4) , USP ((b) (4) Tablet) Lot #(b) (4) was stored in the warehouse which is not secured and which lacks adequate climate monitoring.

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PRODUCTION SYSTEM

OBSERVATION 6

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess. Specifically,

A) No process validation has been performed for OTC drug product (b) (4), USP ((b)(4) Tablet), which is not in accordance with the firm's established written procedure, SOP-25 "Process Validation" which requires validation of processes to confirm that a process consistently produces products that meet predetermined quality and safety standards. Two lots of (b) (4), USP ((b)(4) Tablet) were manufactured and released in (b) (4).

B) On 01/14/2026, our observation of tablet compression for (b) (4) Lot #(b) (4) revealed a lack of batch records on the production floor to ensure consistent batch manufacturing and contemporaneous documentation of production activities. Upon request of the blending and compression batch records for (b) (4) Lot #(b) (4), the Blending Operator provided incomplete batch records which did not include any batch identification, preventing traceability.

OBSERVATION 7

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product. Specifically,

No Bulk hold time studies have been conducted for (b) (4) blend. During the facility walkthrough on 01/13/2026, we observed blended (b) (4) Lot #(b) (4) (Blended on (b) (4)) stored in the manufacturing area corridor prior to beginning compression on (b) (4). On (b) (4) compression of (b) (4) Lot #(b) (4) was paused due to supposed sticking and breaking issues encountered during the compression process. Compression operations for (b) (4) Lot #(b) (4) resumed on (b) (4); however, compression was suspended again on the same date due to a supposed oil-related issue with the equipment. Compression activities remain on hold pending repair of damages to HEPA filters observed in the

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compression room during the facility walkthrough on 01/21/2026; while awaiting repairs the (b) (4) Lot # (b) (4) blend is being stored in a warehouse that is not continuously monitored for temperature excursions.

OBSERVATION 8

Batch production and control records do not include the specific identification of each batch of component and in-process material used for each batch of drug product produced. Specifically,

The batch records for OTC drug product (b) (4), USP ((b) (4) Tablet) Lot # (b) (4) and Lot # (b) (4) do not include the distinctive lot identification of the raw material (active pharmaceutical ingredients and excipients) used in the manufacturing of the drug product.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 9

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

A) No Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) have been conducted for the Tablet Press (b) (4) (Room (b) (4) Room) which was used in the compression of OTC drug product (b) (4), USP ((b) (4) Tablet) manufactured in (b) (4) to ensure the equipment is suitable for its intended use.

B) The Installation & Operational Qualification (NYN-IQ/OQP-001) and Performance Qualification (NYN-PQ-001) for the packaging Line is deficient for the following reasons:
   1. During the review of batch packaging records for the OTC Drug products listed in the table below, we observed that some packaging line setting parameters set during batch startup were not qualified during IQ/OQ and some critical tests were not performed during batch start up:

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Packaging Line Setting Parameter	(b) (4) (b) (4) **tablet Lot #**(b) (4)	(b) (4) (b) (4) **tablet Lot #**(b) (4)	(b) (4) (b) (4) **tablet Lot #**(b) (4)	**IQ/OQ**
Counting Machine Vibrator Speed	Vibrator (b) (4) (b) (4)	Vibrator (b) (4)	Vibrator (b) (4)	Operating ranges during the functionality test are not specified.
	Vibrator (b) (4)	Vibrator	Vibrator	
	Vibrator (b) (4)	Vibrator	Vibrator	
Metal Detector	Not performed	Not performed	Not performed	Does not specify what metal contaminants (ferrous, non-ferrous, stainless steel etc.) or what sizes were used to qualify the metal detector and reject system
Capping Machine	Spindle Speed: (b) (4)	Spindle Speed: Not documented	Spindle Speed: (b) (4)	No Functionality test conducted.
	Gripper Speed: (b) (4)	Gripper Speed: Not documented	Gripper Speed: (b) (4)	

2. The product ran during the packaging line Performance Qualification (PQ) (NYN-PQ-001) is not documented in the PQ datasheet. No testing was conducted on the critical quality attributes of the product utilized. Key parameters, including but not limited to, the batch size, duration, minimum and

maximum fill volumes and line speed, are not specified in the executed PQ datasheet. Additionally, discrepancies were noted between the planned and actual Performance Qualification conditions. For example, the firm conducted (b) (4) trials during PQ and in the (b) (4) trial, the firm deviated from the planned protocol by using a (b) (4) bottle instead of the specified (b) (4) bottle, and only 30 tablets were dispensed per bottle rather than the (b) (4) tablets specified in the protocol.

OBSERVATION 10

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

A) Your firm has not performed cleaning validation studies and established clean hold times and dirty hold times for equipment, including, but not limited to, the Mixing Machine (b) (4), used to manufacture both dietary supplements and drug products to prevent cross-contamination as required per SOP-26 "Cleaning Validation". On 01/09/2026, the (b) (4) for OTC drug product (b) (4) (no lot number was listed in the usage and cleaning logbook) was blended in Mixing Machine (b) (4) following the blending of dietary supplement (b) (4) on the same equipment.

B) Usage and cleaning are not always documented in the usage and cleaning logbooks for each equipment used to manufacture and/or package OTC drug products. Additionally, your firm uses a cleaning solution prepared with (b) (4) and city water; however, the composition and preparation details of cleaning solutions used for cleaning equipment are not documented in the equipment usage and cleaning logbooks. In addition, the cleaning procedures do not include sufficient detail to ensure consistent cleaning.

C) According to SOP-97 "Usage of (b) (4)" and CAPA NYM-CAPA-25-008, the firm is required to perform (b) (4) swab sampling for cleaning verification after each batch. However, the firm failed to conduct swab sampling after blending dietary supplement (b) (4) Lot #(b) (4) on (b) (4) on Mixing Machine (b) (4), which was

processed immediately before an (b) (4) lot (no lot number included). Additionally, no swab sample was collected after the blending of the respective (b) (4) lot.

OBSERVATION 11

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

On 01/21/2026, visible damage and black/brown stains were observed on the HEPA filters on the ceiling in Compression Room (b) (4) above the (b) (4) Tooling Tablet Press (b) (4) which was used to compress (b) (4) tablets Lot #(b) (4). No preventative maintenance program exists for the HEPA filters.

MATERIAL SYSTEM

OBSERVATION 12

Drug products are not stored under appropriate conditions of temperature, humidity and light so that their identity, strength, quality, and purity are not affected. Specifically,

A) No continuous temperature monitoring is conducted of the manufacturing corridor areas where drug products are held. During the facility walkthrough on 01/13/2026, we observed blended (b) (4) Lot #(b) (4) (Blended on (b) (4)) stored in the manufacturing area corridor where temperature is only monitored (b) (4) using a (b) (4) thermohygrometer.

B) No temperature and relative humidity (RH) mapping studies were conducted during the summer for the warehouse where active pharmaceutical ingredients (APIs) and raw materials are stored. Additionally, the mapping studies conducted during the spring, fall, and winter are insufficient, as data collection was limited to (b) (4) within the warehouse with manual readings taken only (b) (4) over (b) (4) period preventing identification of hot and cold spots in the warehouse. In addition, there is no routine continuous temperature monitoring of the warehouse; a (b) (4) temperature value is recorded (b) (4) using a (b) (4) thermohygrometer. On

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01/16/2025, APIs (b) (4) (Vendor Lot (b) (4)) and (b) (4) USP (Vendor Lot (b) (4)) were among materials being stored in the warehouse; the label on the (b) (4) container states to store at (b) (4).

OBSERVATION 13

Specific identification tests are not conducted on components that have been accepted based on the suppliers report of analysis. Specifically,

No comprehensive testing was conducted to establish the reliability of the API (b) (4), USP vendor which is not in accordance with section 5.5 of SOP-20 "Vendor Qualification". The SOP requires that "in addition to the questionnaire, a sample of the material supplied by the vendor in question will be tested accordingly". SOP-20 lacks specific instructions regarding the number of material lots to be evaluated during vendor qualification/requalification and the types of testing required to verify vendor adherence to specifications. Additionally, at least one specific identity test for API (b) (4), USP is not performed routinely; according to the firm's R&D Specialist, certificates of analysis from the vendor are accepted in lieu of identity testing for some batches. Per SOP-30 "Receiving & Storage of Raw Materials", identification testing is mandatory for all incoming raw materials.

OBSERVATION 14

Procedures describing the warehousing of drug products are not established and followed. Specifically,

Materials stored in the warehouse are not appropriately labeled with their disposition status to prevent use of unapproved materials in manufacturing operations. On 01/16/2026, the Interim Production Supervisor stated that (b) (4) of API (b) (4) USP in the warehouse were under quarantine status due to customer cancellation of the manufacturing order. However, during our walkthrough of the warehouse conducted on 01/16/2026, the respective (b) (4) USP (b) (4) were not labeled to reflect its quarantine status. Additionally, the Interim Production Supervisor indicated that API (b) (4) (Vendor Lot (b) (4)) had been released; however, the (b) (4) of API (b) (4) (b) (4) lacked appropriate labeling to identify its released disposition.

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PACKAGING AND LABELING SYSTEM

OBSERVATION 15

Strict control is not exercised over labeling issued for use in drug product labeling operations. Specifically,

A) The room used to store labels of OTC drug products is not access controlled. During our walkthrough of the label room on 01/13/2026, rolls of (b) (4) tablet drug product labels were observed in the label room. On 01/14/2026, during our walkthrough of the label room, these labels were no longer present. According to the Interim Production Supervisor, the labels had been packed for shipment and return to the supplier; however, there was no documentation in the Label Room Log to trace the movement of labels.

B) Batch production records for OTC drug products, including but not limited to (b) (4) tablet Lot #(b) (4), (b) (4) tablet Lot #(b) (4) and (b) (4) tablet Lot #(b) (4), lacked the following documentation:

- Packaging and label reconciliation to ensure accountability of materials used in packaging and labeling operations.
- Examination of packaging and labeling materials prior to packaging operations.
- Lot numbers of packaging materials used in packaging operations on the material data sheet.

DIETARY SUPPLEMENTS

OBSERVATION 16

Your batch production record did not include all required information. Specifically,

You manufactured (b) (4) Tablet, Batch No #: (b) (4), which was distributed on 4/30/25. The following was observed:

- The batch manufacturing record was not reviewed and signed off as closed.

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- The master batch packaging record was not completed in its entirety and not reviewed and approved by QA.

In addition, the following was observed regarding (b) (4) Capsule, Batch No #: (b) (4), which was approved and distributed on 04/28/25:

- The master batch packaging record shows the reconciliation as 73.60% and should fall within (b) (4). The procedure states if the yield is outside the limits, investigation shall be carried out. However, there was no investigation and was checked off as "complies."

OBSERVATION 17

Your batch production record did not include complete information relating to the production and control of each batch. Specifically,

Your written standard operating procedure SOP No. 28 titled "Batch Manufacturing Record" states that a list of raw materials used in the batch, including their sources, batch or lot numbers, and quantities would be included in the batch manufacturing record. However, the following was observed:

- (b) (4), and (b) (4) were used to manufacture your (b) (4) Tablet, Batch No #: (b) (4). There is no batch or lot numbers listed for these components in your batch manufacturing record, and you do not have any other documentation allowing you to identify the batch or lot numbers of the components to the (b) (4) Tablet, Batch No #: (b) (4). (b) (4) Tablet, Batch No #: (b) (4) was distributed on 04/30/25.

- (b) (4), and (b) (4) Capsules were used to manufacture your (b) (4) Capsule, Batch No #: (b) (4). There is no batch or lot numbers listed for these components in your batch manufacturing record, and you do not have any other documentation allowing you to identify the batch or lot numbers of the components to the (b) (4) Capsule, Batch No #: (b) (4). (b) (4) Capsule, Batch No #: (b) (4) was approved and distributed on 04/28/25.

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In addition, the following was observed in the batch manufacturing record for (b) (4) Tablet, Batch No #: (b) (4):

- Step No. (b) (4) of the "Blending" section states Room No. (b) (4) and Blender ID: (b) (4) were used for blending. Step No. (b) (4) of the "Blending" section states to make an entry into the (b) (4) Blender Cleaning and Usage Log of the (b) (4) and (b) (4). I reviewed the logbook titled "EQUIPMENT USAGE & CLEANING LOGBOOK – Mixing Machine (b) (4)," and there is no entry of (b) (4) Tablet, Batch No #: (b) (4) using this equipment. Step No. (b) (4) was initialed in the batch manufacturing record as done and checked by QA.

- Step No. (b) (4) of the "Compression" section states Room (b) (4) Tablet Deduster (b) (4) ID: (b) (4), Metal Detector (b) (4) ID: (b) (4), Tablet Press ID: (b) (4), Tablet Deduster (b) (4) ID: (b) (4), and Metal Detector (b) (4) ID: (b) (4) were used for compression. Step No (b) (4) of the "Compression" section states to record the batch information in the Tablet Press, Tablet Deduster, and Metal Detector Usage and Cleaning Logbooks. I reviewed the logbook titled "EQUIPMENT USAGE & CLEANING LOGBOOK – B-Tooling Tablet Press-(b) (4)," and there is no entry of (b) (4) Tablet, Batch No #: (b) (4) using this equipment. In addition, you do not have the tablet deduster and metal detector usage and cleaning logbooks. Step No. (b) (4) was initialed in the batch manufacturing record as done and checked by QA.

Also, the following was observed in the batch manufacturing record for (b) (4) Capsule, Batch No #: (b) (4):

- Step No (b) (4) of the "Blending" section states Room No. (b) (4) and Blender ID: (b) (4) were used for blending. Step No. (b) (4) of the "Blending" section states to make an entry into the (b) (4) Blender Cleaning and Usage Log of the Start Time and End Time of Use. I reviewed the logbook titled "EQUIPMENT USAGE & CLEANING LOGBOOK – Mixing Machine (b) (4)," and there is no entry of (b) (4) Capsule, Batch No #: (b) (4) using this equipment. Step No. (b) (4) was initialed in the batch manufacturing record as done and checked by QA.

- Step No. (b) (4) of the "Encapsulation" section states Room (b) (4), Encapsulation Machine ID: (b) (4) Capsule Polisher ID: (b) (4), and Metal Detector ID (b) (4) were used for encapsulation. Step No.

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DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New Jersey District Office 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 Ph: (973)331-4900 Industry Information: www.fda.gov/oc/industry	01/13/2026-01/27/2026* FEI NUMBER 3024366553
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Mr. Keyur Patel, Interim Production Supervisor	
TO: FIRM NAME Neeyaan LLC	STREET ADDRESS 4 Corporate Dr
CITY, STATE, ZIP CODE, COUNTRY Cranbury, NJ 08512	TYPE ESTABLISHMENT INSPECTED Manufacturer

(b) (4) of the "Encapsulation" section states to record the batch information in the Encapsulation Machine, Capsule Polisher, and Metal Detector Usage and Cleaning Logbooks. I reviewed the logbook titled "EQUIPMENT USAGE & CLEANING LOGBOOK – Encapsulation Machine (b) (4)," and there is no entry of (b) (4) Capsule, Batch No #: (b) (4) using this equipment. In addition, you do not have the capsule polisher and metal detector usage and cleaning logbooks. Step No. (b) (4) was initialed in the batch manufacturing record as done and checked by QA.

OBSERVATION 18

For component(s) used in the manufacture of a dietary supplement, you did not establish identity specifications, necessary specifications to ensure the specifications for purity, strength, and composition of the dietary supplement are met, and limits on contamination to ensure the quality of the dietary supplement. Specifically,

Specifications for purity, strength, composition, or limits on contamination have not been established for:

- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4) Capsules

Also, you use FTIR as the method to test for the identity of (b) (4) This is not an appropriate method to test the identity for (b) (4)

These components were used in the (b) (4) Capsule, Batch No #: (b) (4), which was approved and distributed on 04/28/25.

Additionally, specifications for purity, strength, composition, or limits on contamination have not been established for:

(b) (4)

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These components were used in the (b) (4) Tablet, Batch No #: (b) (4) which was distributed on 04/30/25.

OBSERVATION 19

You did not conduct appropriate tests or examinations or rely on a certificate of analysis to determine whether components met established specifications. Specifically,

You manufactured (b) (4) Tablet, Batch No #: (b) (4), which was distributed on 4/30/25. The following was observed:

- You provided a certificate of analysis using Neeyaan letterhead dated 04/05/2025 indicating (b) (4) Batch No: (b) (4) was used to manufacture (b) (4) Tablet, Batch No #: (b) (4). You do not conduct testing in-house and use a third-party lab for testing. You do not have raw material testing records from the lab to demonstrate testing was performed. In addition, there is no documentation to confirm (b) (4) Batch No: (b) (4) was used to manufacture (b) (4) Tablet, Batch No #: (b) (4).

- You provided a certificate of analysis using Neeyaan letterhead dated 03-14-2025 indicating (b) (4) Batch No: (b) (4) was used to manufacture (b) (4) Tablet, Batch No #: (b) (4). You do not conduct testing in-house and use a third-party lab for testing. You do not have raw material testing records from the lab to demonstrate testing was performed. In addition, there is no documentation to confirm (b) (4) Batch No: (b) (4) was used to manufacture (b) (4) Tablet, Batch No #: (b) (4).

- You provided a certificate of analysis using Neeyaan letterhead dated 02-20-2025 indicating (b) (4) Batch No: (b) (4) was used to manufacture (b) (4) (b) (4) Tablet, Batch No #: (b) (4). You do not conduct testing in-house and use a third-party lab for testing. You do not have raw material testing records from the lab to demonstrate testing was performed. In addition, there is no documentation to confirm (b) (4) Batch No: (b) (4) was used to manufacture (b) (4) Tablet, Batch No #: (b) (4)

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In addition, you manufactured (b) (4) Capsule, Batch No #: (b) (4), which was approved and distributed on 04/28/25. The following was observed:

- You provided a certificate of analysis using Neeyaan letterhead dated 03-16-2025 indicating (b) (4) Batch No: (b) (4) was used to manufacture (b) (4) Capsule, Batch No #: (b) (4). You do not conduct testing in-house and use a third-party lab for testing. You do not have raw material testing records from the lab to demonstrate testing was performed.

OBSERVATION 20

Your quality control operations did not include determining whether each finished batch conforms to established product specifications. Specifically,

You manufactured (b) (4) Tablet, Batch No #: (b) (4), which was distributed on 4/30/25. You provided a certificate of analysis using Neeyaan letterhead dated 05-22-2025. You do not conduct testing in-house and use a third-party lab for testing. You do not have testing records from the lab to demonstrate testing was performed.

In addition, you manufactured (b) (4) Capsule, Batch No #: (b) (4), which was approved and distributed on 04/28/25. You provided a certificate of analysis using Neeyaan letterhead dated 05-19-2025. You do not conduct testing in-house and use a third-party lab for testing. You do not have testing records from the lab to demonstrate testing was performed.

OBSERVATION 21

You did not follow written procedures for quality control operations. Specifically,

Your written standard operating procedure SOP No. 41 titled "Finish Product Release & Distribution" states QA shall review and approve the release of finished products for distribution, with the review criteria including compliance with all manufacturing, packaging, and labeling procedures and specifications; satisfactory test results and inspection findings; and completed and approved documentation, including batch records and investigation reports. However, your certificate of analysis for (b) (4) Tablet, Batch No #: (b) (4) was signed as approved on 05/22/2025, which is after the distribution date of 4/30/25.

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In addition, your certificate of analysis for (b) (4) Capsule, Batch No #: (b) (4) was signed as approved on 05/19/2025, which is after the distribution date of 04/28/25.

OBSERVATION 22
Your quality control personnel did not conduct a material review and make a disposition decision when a batch deviated from the master manufacturing record. Specifically,

You manufactured (b) (4) Capsule, Batch No #: (b) (4), which was approved and distributed on 04/28/25. The following was observed:

- The batch manufacturing record shows the (percentage) % actual yield was 86.47%. The procedure states that if the yield or reconciliation falls outside the acceptable limits (b) (4) to promptly report the discrepancy to the supervisor and not to proceed with further processing until approval is received from QA. However, there is no documentation in your Out of Specification Logbook or Deviation Logbook.

OBSERVATION 23
You did not establish product specifications for identity. Specifically,

You manufactured (b) (4) Tablet, Batch No #: (b) (4), which was distributed on 4/30/25. Your finished dietary supplement product specification for identity lists (b) (4) as the method reference. The method states "Assay results are derived from the batch manufacturing record (BMR) as part of production and process control." This is not a scientifically valid method.

OBSERVATION 24
You did not establish specifications to ensure that you applied the specified label. Specifically,

Finished dietary supplement labels are provided by your customers. You do not have specifications to ensure that you applied the specified label.

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OBSERVATION 25

You did not establish packaging specifications. Specifically,

You procure the packaging for finished dietary supplements. Packaging specifications were requested, and you stated that you do not have packaging specifications.

***DATES OF INSPECTION**

1/13/2026(Tue), 1/14/2026(Wed), 1/15/2026(Thu), 1/16/2026(Fri), 1/21/2026(Wed), 1/23/2026(Fri), 1/27/2026(Tue)

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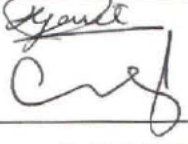
SEE REVERSE OF THIS PAGE		Janet A. Rajan, Investigator Charlotte P. Chang, Investigator	01/27/2026

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."