DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	5/5/2026-5/15/2026* FEI NUMBER 1314625

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Julien NMI Seid, General Manager

FIRM NAME	STREET ADDRESS
Unither Manufacturing LLC.	755 Jefferson Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rochester, NY 14623-3233	Sterile & Non-Sterile Drug 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:

OBSERVATION 1

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

Specifically,

a) On 01/18/2026, your firm performed a (b) (4) Media Fill on (b) (4) Line (b) (4) per Validation Protocol 24-PQ-3243-00 following repair of the (b) (4) unit. The (b) (4) non-sterile media fill (Lot # (b) (4)), which (b) (4) followed by a (b) (4) when filled at the (b) (4) unit failed, with all integral (b) (4) vials testing positive for microbial growth, as documented in Deviation Report PR177900. Your firm subsequently performed a repeat media fill on 02/10/2026 which was deemed to be successful; however, the repeat was not conducted under the same conditions as the original failed media fill. Instead, a (b) (4) was used to transfer bulk media from the manufacturing tank to the holding tank, whereas the firm's current commercial process for (b) (4) (Batch Size: (b) (4)) and (b) (4) (Batch Size: (b) (4)) utilizes a (b) (4) for this same bulk transfer step.

b) Your media fills performed on (b) (4) Lines (b) (4) are not representative of commercial sterile (b) (4) production conditions. Each year, your firm performs (b) (4) Media Fills on (b) (4) line to qualify the filling duration of commercial sterile (b) (4) products. The (b) (4) Media Fill is conducted by (b) (4). However, commercial (b) (4) products on these lines have a filling duration between (b) (4), which is significantly longer than the subsequent (b) (4) established in the (b) (4) Media Fill run. A media fill of approximately (b) (4) does not adequately simulate worst-

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	Syeda N Mahazabin, Investigator Divek R Jumani, Investigator Young K Chou, Investigator	X Syeda N Mahazabin Investigator Signed By: Syeda N. Mahazabin - S Date Signed: 05-15-2026 12:03:41	5/15/2026

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case filling conditions and does not provide sufficient evidence that the aseptic (b) (4) filling process can consistently maintain microbial control over the full duration of a commercial filling operation.

OBSERVATION 2

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically,

a) Your firm does not perform Total Yeasts and Molds Count (TYMC) or have data to support the efficacy of the preservatives to support the claimed shelf life on the (b) (4) product line shown below under various product labeling and configurations prior to release or on stability:

Product Name	Approximate Number of Batches Released Since September 2024
(b) (4)	

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(b) (4)

b) Your firm has not performed preservative efficacy testing on (b) (4) Suspension that contain preservative, (b) (4) Since September 2024, your firm has released approximately (b) (4) batches of (b) (4) Suspension with the labeled shelf life of (b) (4) by conducting a quantitative testing on this preservative only.

OBSERVATION 3

Input to and output from the computer, related systems of formulas and records or data are not checked for accuracy.

Specifically,

Your firm uses (b) (4) instruments to perform post-use (b) (4) testing on product (b) (4). Per ROC-SOP-0039, (b) (4) Test System-(b) (4), Effective Date 07/31/2024, repeat testing is permitted a maximum of (b) (4) times. During the facility walkthrough conducted on 05/06/2026, it was observed that multiple test runs were aborted, multiple runs resulted in error messages, and (b) (4) testing was repeated up to five times on a (b) (4), exceeding the maximum number of attempts permitted by the SOP without justifications or Quality Assurance (QA) oversight. Additionally, your firm has not established a procedure for audit trail review of the (b) (4) instrument, and QA does not perform any review of the instrument's audit trail to detect or evaluate such occurrences.

OBSERVATION 4

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

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Specifically,

a) The firm's visual inspection qualification program (Risk Assessments 24-RA-3264-00 and 24-RA-3264-01) qualifies Microbiologists using (b) (4) particulates only; however, the same risk assessments identify a broad range of particle types from documented manufacturing and filling failure modes, including (b) (4) particles. Although (b) (4) and certain other colored particles are characterized as "(b) (4) particles," no qualification data are provided to demonstrate that (b) (4)-particle test (b) (4) are representative substitutes for the full range of particle colors and materials identified within.

b) The aforementioned qualification program specifies a Probability of Detection (PoD) of (b) (4)% for particles (b) (4) microns, yet the firm's risk assessments acknowledge that visible particles may range from 50 to 500 microns, consistent with USP <790> and USP <1790>. No scientific justification has been provided specific to the firm's products, container types, and inspection conditions to support the selection of (b) (4) microns as the qualification threshold.

c) The firm samples (b) (4) vials for destructive visual inspection from batches ranging from approximately (b) (4) to (b) (4) vials (Risk Assessments 24-RA-3264-00 and 24-RA-3264-01; SOP ROC-SOP-0871), representing a sampling fraction as low as (b) (4)% for the largest batches. Although up to (b) (4) vials are collected at (b) (4) intervals every (b) (4) across the filling process, only (b) (4) are subjected to visual inspection testing.

OBSERVATION 5

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

Specifically,

Your firm has not performed forced degradation studies to identify and evaluate potential degradants, if

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any, that may form throughout the labeled shelf life of the following sterile (b) (4) finished drug products. As such, your firm does not conduct impurity testing as part of finished product release testing or stability testing for these products:

(b) (4)

OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate standards and test procedures designed to assure that in-process materials conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Bioburden method suitability studies for (b) (4) Bulk are inadequate per Report # R16123 dated 11/21/2016. In R16123, method suitability testing was performed on a (b) (4), post-sterilization finished product rather than pre-sterilization bulk product used in routine bioburden

testing. However, your firm did not provide any scientific justification to demonstrate the equivalency between the pre and post sterilized drug products with this approach. Furthermore, this bioburden method was extended to (b) (4) Bulk, which contains (b) (4)% less (b) (4) than (b) (4) Bulk without independent suitability testing or a documented risk assessment to evaluate whether this formulation difference could affect microbial recovery.

OBSERVATION 7

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,

The dedicated (b) (4) (Equipment ID: (b) (4)) used in the production of (b) (4) Suspension, (b) (4)) and (b) (4) Suspension (b) (4)) is cleaned (b) (4) as per MC-0043, Cleaning of the (b) (4) (b) (4) without any cleaning validation to support the established cleaning frequency.

REPEAT OBSERVATION FROM SEPTEMEMBER 2024.

OBSERVATION 8

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

Specifically,

Your firm conducted (b) (4) requalification temperature mapping studies across (b) (4) warehouse locations at two (2) sites (b) (4) (Warehouse Areas (b) (4)) (b) (4) square feet and (b) (4) (b) (4) square feet used for the storage of finished drug products. These studies are inadequate due to:

a) No documented scientific rationale for the selection of a (b) (4) study duration. Your firm stores

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finished drug products for approximately (b) (4) (filled capsules), (b) (4) (non-sterile liquids), and (b) (4) (sterile liquids). A (b) (4) study captures less than (b) (4) % of the maximum product storage duration and is insufficient to characterize the full range of thermal variability to which stored product is exposed.

b) Lack of incorporation of external ambient temperature data into any of the (b) (4) warehouse requalification temperature mapping studies. Without correlation to outdoor temperature conditions during the study periods, there is no scientific rationale that the (b) (4) windows selected for summer (b) (4)) and winter ((b) (4)) represent the most thermally challenging conditions experienced by the warehouses across those seasons.
Currently, you are storing multiple lots of finished drug products across these inadequately evaluated warehouse locations, including but not limited to:

- (b) (4) Suspension (b) (4) : Lot (b) (4) , Qty (b) (4) , Exp: (b) (4) Location: (b) (4) ((b) (4) .)
- (b) (4) : Lot (b) (4) Qty: (b) (4) , Exp: (b) (4) , Location: (b) (4) ((b) (4))
- (b) (4) : Lot (b) (4) Qty (b) (4) , Exp: (b) (4) Location: (b) (4) ((b) (4))
- (b) (4) : Lot (b) (4) Qty: (b) (4) Exp: (b) (4) , Location: (b) (4) ((b) (4))

(b) (4) : Lot (b) (4) Qty: (b) (4) , Exp (b) (4) , Location (b) (4) (Clay Rd.) (b) (4) Capsule: Lot (b) (4) , Qty: (b) (4) Exp: (b) (4) , Location (b) (4) ((b) (4) .)

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OBSERVATION 9

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

Specifically,
Your firm failed to follow procedure OP-0138-038 (Rochester Site Deviation Management System, effective 02/02/2026), Section 5.7, which requires that deviation investigations be completed within (b)(4) of the (b)(4) record being opened. The same section further requires that when an investigation cannot be completed within (b)(4), a documented justification must be entered including the rationale for remaining open, a summary of work completed to date, the expected closure date, and the initials and date of the person making the entry.

During the inspection, it was observed that numerous deviation and laboratory investigation records (LIRs) remained open well beyond the (b)(4) requirement established in OP-0138-038, without documented updates or justification in (b)(4) to support the extended timelines. A review of the firm's deviation records from September 2024 through May 2026 identified approximately 70 or more deviations that remained open at the initiation of inspection, including, but not limited to:

PR#	Open Date	Description
170256	08/26/2025	Sample Site (b)(4) Above the Acceptable Limit for (b)(4) Cleaning Bioburden for Line (b)(4)
171192	09/16/2025	(b)(4) EM Sample Site (b)(4) in Room (b)(4) (b)(4)) over limit for (b)(4) lot (b)(4)
175501	12/17/2025	(b)(4) bioburden results for batch # (b)(4) exceeded the specification of (b)(4), with results of >2,000 CFU/100 mL and >120 CFU/100 mL.

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*DATES OF INSPECTION

5/05/2026(Tue), 5/06/2026(Wed), 5/07/2026(Thu), 5/08/2026(Fri), 5/11/2026(Mon), 5/12/2026(Tue), 5/13/2026(Wed), 5/14/2026(Thu), 5/15/2026(Fri)

X Young K Chou
Investigator
Signed By: 2003017860
Date Signed: 05-15-2026 12:05:20

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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."