DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Detroit District Office 300 River Place. Suite 5900 Detroit, MI 48207 (313) 393-8100	07/14/2025 - 07/24/2025 FEI NUMBER 3005946041

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mirna Hanna, Vice President of Pharmacy Operations & Compliance

FIRM NAME	STREET ADDRESS
Mixlab WI LLC	407 West Silver Spring Drive
CITY, STATE, ZIP CODE, COUNTRY Milwaukee, WI 53217	TYPE ESTABLISHMENT INSPECTED Producer of non-sterile drug products

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

Specifically,

A. The written procedure, SOP MLWI-001-04, titled "Non-Sterile Compounding Area", Revision 2.0, is not consistently followed. As specified in Section 3.9.1, the minimum garb required to enter the compounding area includes a reusable lab coat, shoe covers, Hair/bear net, and N95 mask or respirator. When gowns are reused, they must remain within the compounding area and may only be reused during the (b)(4) However, employees were observed donning gloves and shoe covers upon entry through the back door, proceeding through the compounding area to the basement to put on their gowns, and then re-entering the compounding area.

B. The written procedure, SOP MLWI-001-05, titled "Non-Sterile HD Compounding Area," Revision 2.0, is not always followed. As specified in Section 3.3, non-sterile hazardous drug (HD) compounding and HD storage must occur in a Containment Segregated Compounding Area (C-SEC) that is separate from non-HD compounding and/or non-HD storage. However, on 7/15/2025, a pharmacy technician was observed filling Methimazole (6mL pen) 2.5mg/0.1mL, Transdermal, Lot (b)(4) quantity - pens, in the non-HD compounding area.

C. The written procedure, SOP MLWI-001-03, titled "Non-HD and HD Cleaning Procedures", Revision 2.0, is not followed. Cleaning instructions for work surfaces and all reusable

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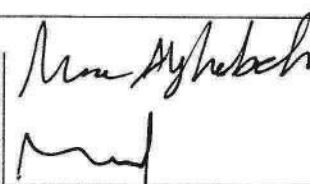
SEE REVERSE OF THIS PAGE	Muna Algharibeh, Investigator Tiffani Turinski, Veterinary Medical Officer Andy J. Barrowcliff, Branch Chief		07/24/2025

equipment, including glassware and utensils, as outlined in sections 3.4.1 of the SOP, Non-HD Compounding, and section 3.4.2, HD Compounding, are not being followed. For example,

1. The firm is not using a lab-grade detergent (e.g., (b)(4) for cleaning glassware and utensils, as required by SOP MLWI-001-03. Instead, a household cleaning agent not intended for pharmaceutical use is being used to clean reusable equipment, including glassware and utensils utilized in HD compounding.

2. Failure to apply and document the required contact time for the cleaning agent on work surfaces as specified in SOP MLWI-001-03.

3. Ceilings were not cleaned at the frequency specified in SOP MLWI-001-03, despite visible soiling and potential surface contamination (e.g., from splashes). Staining was observed on the ceiling in the HD compounding area, consistent with forceful pumping—potentially drug product or adhesive residue.

D. The written procedure, SOP MLWI-001-03, titled "Non-HD and HD Cleaning Procedures", Revision 2.0, is not followed. Attachment 2, titled "Minimum frequency for Cleaning and Sanitizing in Nonsterile Compounding Areas and Surfaces", specifies that the minimum frequency for cleaning and sanitizing work surfaces is at the (b)(4) However, employees were observed performing cleaning only between compounding activities. There were no records documenting cleaning at the (b)(4)

OBSERVATION 2
The master production and control records are not followed.

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A. Fluoxetine USP API is light sensitive. On July 17, 2025, during the compounding of Fluoxetine micro-tab 8mg tablets, Lot (b)(4), it was observed that the operator did not follow the batch record instructions related to (b)(4) to protect the final preparation from light while still allowing air circulation during the [redacted] process.

B. On July 17, 2025, during the compounding of Methimazole Minimix 2.5 mg Chew Treat (Lot (b)(4), it was observed that the operator used a mortar and pestle instead of the [redacted] instrument mixing method ((b)(4)) as specified in the batch record. Additionally, the required (b)(4) time was not followed or documented.

C. On July 16, 2025, during the compounding of Cisapride 3mg CAPSUL [redacted], the operator did not follow the batch record instructions related to (b)(4) to ensure even particle size.

OBSERVATION 3

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

Your firm's batch records do not include documentation and/or complete documentation of each significant step in the production of drug products. For example,

Your firm compounds Methimazole 2.5mg/0.1mL Transdermal and fills it into a [redacted] syringe. The [redacted] syringe is then used to fill Methimazole 2.5mg/0.1mL Transdermal into 1mL, 3mL, 6mL, and 9mL pens. The following was observed upon review of the manufacturing batch record for Methimazole

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(6mL pen) 2.5mg/0.1mL Transdermal, Lot (b)(4) quantity (b)(4) manufactured on (b)(4)

- Your firm does not document complete manufacturing and control instructions for the filling process of the - pens.
- Your firm does not document in the batch record the actual number of 60mL syringes that were used in the filling process.
- Your firm does not document the visual inspection records of the filled pens in the batch record or in any controlled spreadsheet that is part of the batch record. Your firm does not document whether any pens are rejected or the reasons for rejection.
- Explicit instructions for handling hazardous drug (HD) material are not outlined in the manufacturing batch record.

OBSERVATION 4
Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

Your firm did not conduct an in-house efficacy study to verify the sporicidal product's label claim. Instead, the adequacy of the cleaning agent for its intended use was determined based on a review of the efficacy study provided by the cleaning agent manufacturer.

OBSERVATION 5
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.

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Most lots of finished drug product that the firm produces are not tested for potency prior to release. Your firm only tests one lot of each dosage form for each employee once annually as part of the employee qualification process.

OBSERVATION 6

Specific identification tests are not conducted on components that have been accepted based on the supplier's report of analysis.

Specifically,

A certificate of analysis from the supplier is accepted in lieu of testing of each component received. The firm currently neither is testing each component, including excipient and active ingredient, nor has a program to establish the reliability of the supplier.

OBSERVATION 7

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

Specifically,

Your firm does not have a written stability testing program to determine Beyond Use Dates (BUD) placed on all your drug product.

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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."