DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	7/23/2024-8/2/2024* FEI NUMBER 3008790859

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Vinh X. Dam, Chief Pharmacy Officer

FIRM NAME	STREET ADDRESS
Mixlab TX LLC	953 Hilltop Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Weatherford, TX 76086-8811	Producer of sterile and 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 in writing and fully followed.

Specifically,

a) Your firm has no written procedures outlining the responsibilities of the Quality Unit, including release or rejection of finished drug products.

b) Your firm does not have a written procedure describing the process for the release of each lot of sterile and non-sterile drug product produced by your firm. Your firm has an unwritten process whereby lots of sterile drug products are released distribution before your firm has received final sterility test results. Your firm has not defined in a procedure who can release drug product and there is no documentation indicating drug product production and control records have been reviewed and approved] by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

c) Your firm's sterilization cycles used to render several injectable drug products sterile via (b)(4) have not been validated. Please refer to **OBSERVATION 2** for details.

d) Your firm has not validated the cleaning, sterilization and/or (b)(4) process for the stoppers and vials used by your firm to package sterile drug products. Please refer to **OBSERVATION 4** for details.

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	Margaret M Annes, CSO Stephanie M Mongeluzzi, Veterinary Medical Officer	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 08-02-2024 12:52:55	8/2/2024

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e) Media fills performed by your firm with each of the technicians/pharmacists that work in the ISO 5 area do not closely simulate actual production conditions or cover worst case or most challenging conditions. Please refer to **OBSERVATION 2** for details.

f) Your firm is not performing environmental or personnel monitoring in the classified areas (ISO 5/ISO 7/ISO 8) each day that sterile drugs products are produced. Your firm is not performing environmental monitoring during media fills. Please refer to **OBSERVATION 3** for details.

g) Your firm does not conduct routine testing for potency (assay) for all drug products produced by your firm (sterile and non-sterile), with the exception of controlled substances and reversal drugs. Please refer to **OBSERVATION 6** for details.

From April 1, 2024 to July 23, 2024, your firm made approximately (b)(4) lots of sterile drug products and (b)(4) lots of non-sterile drug products.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include validation of the aseptic and sterilization process.

Specifically,

a) Media fills performed by your firm with each of the technicians/pharmacists that work in the ISO 5 area do not closely simulate actual production conditions or cover worst case

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or most challenging conditions. The media fill your firm performs has the technician/pharmacist filling media into (b)(4) vials and media into (b)(4) positive control vials. The vials are received with a kit already stoppered and the media is introduced to the vial using a (b)(4). In routine production, your firm fills various size vials (10mL-100mL vials and 500mL serum bottles). Batch sizes are typically in excess of (b)(4) units and can be as many as (b)(4) units.

For example,

- (b)(4)/100mL vials were filled for lot #DA1236 of Isoflupredone Acetate 2 mg/mL, Injectable Suspension, on 06/24/2024.
- (b)(4)/10mL vials were filled for lot #D383D0 of Detomidine HCl 20 mg/mL, Injectable Solution, on 07/11/2024.

All vials used by your firm are sterilized/(b)(4) by your firm and then filled and stoppered by the technician. Serum bottles are received sterile/(b)(4) and then filled and stoppered by the technician. Your firm uses a (b)(4) and (b)(4) sterilized on site for filling all vials and serum bottles. No product is filled using a (b)(4)

In addition, documentation of the media fills performed are incomplete in that they do not include how the media was prepared, the order in which the vials are filled with media and the volume filled in each, documentation of all consumables used such as (b)(4) (b)(4) and the (b)(4) used to reconstitute the media.

b) Your firm's sterilization cycles used to render injectable drug products sterile via (b)(4) have not been validated. Your firm prepares various drug products from bulk

non-sterile active pharmaceutical ingredients (API) and excipients that can be (b)(4) There are some products where the final product is (b)(4) and others where a component is (b)(4) and added to other (b)(4) components.

Finished drug products that are (b)(4) include:

- Altrenogest 225 mg/mL, Injection
- Diclazuril 500 mg, For Reconstitution
- Guanabenz Acetate 20 mg/mL, Injectable Solution
- Reserpine 2.5 mg/mL, Injectable Solution

Drug products where a component of the final drug product is (b)(4) include:

- Adrenocorticotropic Hormone (ACTH) 80 IU/ml, Injection, 10mL
- Fluticasone Propionate 2 mg/mL + Amikacin Sulfate 50 mg/mL, Injectable Suspension, 10mL
- Isoflupredone Acetate 2 mg/mL, Injectable Suspension,100mL

c) The sterilization cycle used by your firm for the Fluticasone Propionate used in the Fluticasone Propionate 2 mg/mL + Amikacin Sulfate 50 mg/mL, Injectable Suspension, 10mL is not described in the batch record.

d) On July 24, 2024, I observed the technician filling lot #F093B0 of Arginine (L) 100 mg/mL, Injectable Solution, 100mL vials. The technician rested his arms inside the ISO 5 LFH during filling. He wore the same gown earlier inside the ISO 7 Room 125 where formulation of the drug products occur before filling.

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OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

a) Your firm is not performing environmental or personnel monitoring in the classified areas (ISO 5/ISO 7) each day that sterile drugs products are produced. Viable surface sampling is performed (b)(4) and viable active air sampling is performed (b)(4) . Sampling is generally performed at the (b)(4) filling of sterile drug products (b)(4) in the ISO 5 Laminar Flow Hood (LFH). In addition, your firm does not perform non-viable particulate monitoring in the ISO 5 Laminar Flow Hood during production/filling of sterile drug products.

Your firm is not monitoring each operator working in the ISO 5 area and ISO 7 clean room each day drug products are prepared. Your firm is currently sampling the fingertips of operators (b)(4) .

b) Your firm is not performing environmental monitoring during media fills.

OBSERVATION 4

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Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically,

a) Your firm has not validated the cleaning, sterilization and/or (b)(4) process for the stoppers and vials used by your firm to package sterile drug products or the (b)(4) used for filling sterile drug products.

b) Your firm has not validated the re-sterilization and/or (b)(4) of stoppers and glass vials. According to your pharmacist who oversees production of sterile drug products, unused rubber stoppers and glass vials that have already been through your firm's sterilization and/or (b)(4) process can be placed back into inventory and processed again. Your firm has no system for tracking the rubber stoppers and glass vials that may have been subjected to the sterilization/(b)(4) process more than once.

OBSERVATION 5

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, your firm is not testing the Diclazuril 500 mg, For Reconstitution, 50mL for sterility or endotoxin prior to release/distribution. Your firm has made four (4) lots since (b)(4) (lot #s 6A942F, 8A3623, 847FFC, and B47C96). Lot #s 6A942F (BUD: 10/20/2024), 8A3623

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(BUD: 11/10/2024), and 847FFC (BUD: 01/05/2025) have been distributed.

OBSERVATION 6

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, your firm does not conduct routine testing for potency (assay) for all drug products produced by your firm (sterile and non-sterile), with the exception of controlled substances and reversal drugs such as Naltrexone HCl 50 mg/mL, Injectable Solution.

OBSERVATION 7

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

Specifically,

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

Your firm has no written and approved stability protocols and no final written and approved reports. Your firm has not maintained all test results or the original batch record for the lot placed on stability for all drug products to demonstrate no changes have been made to the formulation. The test methods used for assay and sterility

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testing are not validated and/or stability-indicating.

Products that are missing original batch records for the lots placed on stability include but are not limited to the following:

- Sarraceniaceae (Sarracenia/Pitcher Plant) 0.5 mg/mL, Injectable Solution
- Isoflupredone Acetate 2 mg/mL, Injectable Suspension
- Guanabenz Acetate 20 mg/mL, Injectable Solution
- Detomidine HCl 2.5 mg/mL + Xylazine HCl 100 mg/mL, Injectable Solution

b) Your firm has no documentation of a stability study having been performed to justify the 180-day BUD placed on Diclazuril 500 mg, For Reconstitution, 50mL.

c) Your firm has not performed antimicrobial effectiveness testing (AET) per USP <51> for all injections packaged in multiple-dose containers to verify the preservative system is effective and protects the product over its shelf life under expected conditions of use. Drug products packaged in multi-dose vials include but are not limited to: Tolazoline HCl 100mg/mL and 200mg/mL; Altrenogest 225mg/mL; Isoflupredone Acetate 2mg/mL suspension; Amikacin Sulfate 300mg/mL; L-Arginine 100mg/mL; and Reserpine 2.5mg/mL.

OBSERVATION 8

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

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documentation of each significant step in the production of drug products. For example,

a) Your firm is not documenting in the batch record the actual number of biological indicators (BI) used and incubated used when (b)(4) certain drug products.

b) Your firm is not documenting in the batch record sampling performed of finished drug products.

c) Visual inspection of finished sterile drug products is documented on an uncontrolled Excel spreadsheet that is not part of the batch record for each drug product. Your firm is not documenting in the spreadsheet if any vials are rejected or the reason for rejection.

***DATES OF INSPECTION**
7/23/2024(Tue), 7/24/2024(Wed), 7/25/2024(Thu), 7/26/2024(Fri), 7/29/2024(Mon), 7/30/2024(Tue), 7/31/2024(Wed), 8/01/2024(Thu), 8/02/2024(Fri)

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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."