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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 550 Main Street, Ste 4-930<br>Cincinnati, OH 45202<br>(513)322-0700 Fax:(513)679-2772 | 5/6/2025-5/16/2025*<br>FEI NUMBER<br>3025336457 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Emily A. Reyes, VP-Quality and Regulatory Affairs

| FIRM NAME | STREET ADDRESS |
|---|---|
| STAQ Pharma of Ohio, LLC | 255 Phillipi Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Columbus, OH 43228-1307 | Outsourcing Facility |

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

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, you did not perform an investigation to identify the root cause(s) for critical defects observed during the 100% visual inspection and the subsequent Accepted Quality Limit (AQL) inspection process.

You observed particulate matter that you determine to be critical and major defects during the visual inspection of Dexmedetomidine Hydrochloride 4 mcg/mL, 5mL in a 5mL syringe, Lot (b) (4) . The initial 100% visual inspection identified 85 defects (74 critical, 9 major and 2 not classified). After this 100% visual inspection, followed by a failed AQL inspection which identified 1 critical defect. After you confirmed the AQL failure you did not initiate an investigation to determine the root cause of the critical defect. Instead, you performed a second 100% visual inspection for the same lot. The second 100% visual inspection identified 94 defects (87 critical and 7 major categories), which was more than the first 100% visual inspection. Even after observing the 94 defects (87 of which were determined to be critical) you released and distributed the lot. In addition, the particulate (orange particle inside syringe barrel) discovered during the AQL inspection was not characterized, and no corrective actions were implemented.

Dexmedetomidine Hydrochloride 4 mcg/mL, 5mL in a 5mL syringe, Lot (b) (4) , exp. 06/08/2025, was deemed free from defective units and suitable for release. Lot (b) (4) , was released by Quality

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Tekalign Wondimu, Investigator<br>Claude Noel Y Zanetsie, Investigator<br>Yaharn Su, Investigator | X Tekalign Wondimu Investigator Signed By: TEKALIGN WONDIMU -S Date Signed: 05-16-2025 09:43:55 | 5/16/2025 |

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Assurance on 01/30/2025.

**OBSERVATION 2**

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 The acceptance sampling inspection governed by procedure SOP-0052 "Sampling Plans" Rev 2, Effective Date 09 Feb 2024 does not clearly define reinspection parameters, fails to establish scientifically sound acceptance criteria following reinspection, or require lots that fail to meet initial Acceptable Quality Limits (AQL) to be rejected.

B-The 100% visual inspection program governed by procedure OH-SOP-0012 "Visual Inspection – OH" Rev 5, Effective Date 26 Mar 2025 does not establish acceptance criteria for each defect categories (critical, major, or minor defects), and does not require trending of the different defect categories.

C-The use of (b) (4) for inspecting colored vials is not established. Your firm produces methotrexate drug product that are dispensed in amber (colored) vials. Additionally, there is no documentation of under what (b) (4) the product is inspected. (b) (4) used in visual inspection of amber vials are qualified at (b) (4) .

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On 15 Jan 2025, you released (b) (4) vials of Methotrexate 25 mg/mL, 40 mL in 50 mL, lot (b) (4) out of which (b) (4) vials were distributed to a customer.

**OBSERVATION 3**

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, your labels do not include the following information:

Subject to paragraph (B)(i), a list of active ingredient(s), identified by established name and the quantity or proportion of the active ingredient(s).

Examples of your drug product labels that do not contain this information include, but are not limited to:

- Phenylephrine HCl 100 mcg/5 mL
- Succinylcholine Cl 100 mg/5 mL
- Succinylcholine Cl 200 mg/10 mL

***DATES OF INSPECTION**

5/06/2025(Tue), 5/07/2025(Wed), 5/08/2025(Thu), 5/09/2025(Fri), 5/12/2025(Mon), 5/13/2025(Tue), 5/14/2025(Wed), 5/16/2025(Fri)

X Claude Noel Y Zanetsie
Investigator
Signed By: Claude Noel Zanetsie -S
Date Signed: 05-16-2025 09:44:36

X Yaharn Su
Investigator
Signed By: 2004003466
Date Signed: 05-16-2025 09:45:13

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."