DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	7/16/2024-7/26/2024* FEI NUMBER 3010166491

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gulshakar Khwaja, RPH, MS, PharmD., Chief Operating Officer

FIRM NAME	STREET ADDRESS
Nubratori, Inc	381 Van Ness Ave Ste 1507
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Torrance, CA 90501-7220	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 I OBSERVED:

OBSERVATION 1

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

Specifically,

A. You do not perform growth promotion studies on media used during Media Fills. Your firm uses (b) (4), and (b) (4) for your Media Fills and therefore does not have evidence that the media can promote the growth of gram-positive, gram-negative bacteria, yeast, and mold.

B. Your firm has not performed product validation for Dexamethasone 24 mg/ml Injectable, Preservative Free using the final distributed container. During normal production, your firm uses 2mL amber vials, however, all product validation studies and media fills have used 2 mL (b) (4) vials. Dexamethasone 24 mg/ml Injectable is a light sensitive compound.

C. Media fill batch records do not reflect all manipulations performed during normal production.

1. Your firm includes the use (b) (4), however this (b) (4) is not used in any of the (b) (4) sterilized, aseptically filled sterile products.

2. During the compounding of Dexamethasone and Lidocaine/ Tetracaine, your firm uses (b) (4) control vial to compare volume in each vial. These control vials were not included in the media fill.

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	Lucila B Nwatu, Investigator/Consumer Safety Officer X Lucila B Nwatu Investigator/Consumer Safety Officer Signed By: Lucila B. Nwatu -S Date Signed: 07-26-2024 05:16:13	7/26/2024

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OBSERVATION 2

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

Specifically,

On 07/17/2024, during the production of Lidocaine HCl/Tetracaine HCl (Lot# (b) (4)), I observed a technician collect their glove fingertip personnel monitoring samples, after wiping a piece of air sampling equipment with Sterile (b) (4) , and samples were not taken immediately after completion of aseptic operations. Personnel monitoring samples should be taken before planned disinfection. The technicians did not follow the order listed in the Batch Production Record for sampling.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

On 07/17/2024, during the production of Lidocaine HCl/Tetracaine HCl (Lot# (b) (4)), I observed that the operator failed to wipe down the ISO 7 side of the (b) (4) with sterile (b) (4) (b) (4) before opening it to receive materials from the ISO 8 ante room. I observed the operator failed to clean the legs of the ISO 5 (b) (4) air flow hood before aseptic operations.

OBSERVATION 4

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

Specifically,

Your firm's visual inspection program is inadequate.

a. You do not document the complete results of the (b) (4) acceptance rate inspection performed by Quality control after the 100% visual inspection and instead use a stamp to denote approval.

b. Your firm failed to demonstrate that operators can adequately identify defects with the use of (b) (4) during the visual inspection of amber vials. Products filled in amber vials include Dexamethasone Sodium Phosphate Injection and Dexamethasone Sodium Phosphate/Lidocaine HCl Injection.

c. You failed to establish a minimum time for the inspection of each vial against the (b) (4) backgrounds.

d. You firm's defect kit is deficient. The library of defects used to qualify visual inspectors is composed of (b) (4) of which contain multiple defects in each vial. The defect kit is missing extrinsic, intrinsic, or inherent defects to the manufacturing process such as (b) (4) particulates, and therefore there is no assurance that visual inspectors can identify these defects during visual inspection.

e. Your firm failed to establish a statistically sound sampling plan for AQL inspection, that would trigger an investigation and reinspection of the entire batch of sterile finished drug product. Defects are not classified based on risk.

f. You failed to establish a process for incorporating new defects found during production into your defect library.

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OBSERVATION 5

Each lot of a component liable to objectionable microbiological contamination is deficiently subjected to microbiological tests before use.

Specifically,

Acceptance of incoming lots of non-sterile component for use in sterile drug products must include microbial and endotoxin testing and meet limits appropriate for the drug product's intended use. Your firm failed to perform microbial and endotoxin testing on all lots of the following Bulk Drug Substances (BDS):

- Dexamethasone Sodium Phosphate
- Lidocaine
- Tetracaine HCl

These BDS were used to compound the following sterile finished products:

- Dexamethasone Sodium Phosphate 24 mg/ml Injectable, Preservative Free, Lot #(b) (6), (b) (7)(C), BUD 01/19/2025
- 0.4% Lidocaine HCl with 0.2% Tetracaine HCl Injection, Preservative Free, Lot #(b) (6), (b) (7)(C) BUD 03/14/2025

OBSERVATION 6

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

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Your firm failed to conduct full testing as part of the Bulk Drug Substance (BDS) (b) (4) re-qualification of supplier qualification. Your firm's written procedure is inadequate as section 5.1.4 states "(b) (4) Your firm has not performed full testing of incoming raw materials from its BDS supplier, since 2019, which applies to the following BDS:

- Dexamethasone Sodium Phosphate (Lot #(b) (4)),
- Lidocaine HCl (Lot #(b) (4)),
- Tetracaine HCl (Lot #(b) (4)),
- Baclofen (Lot #(b) (4)),
- Diclofenac Sodium (Lot #(b) (4)),
- Gabapentin (Lot #(b) (4)),
- Ketamine HCl (Lot #(b) (4)),
- Ketoprofen (Lot #(b) (4)),
- Naltrexone (Lot #(b) (4)).

OBSERVATION 7

Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

The following product was compounded and not identified on your report dated December 2022.

- Diclofenac Sodium 40 mg/2.5 g (16 mg/1g) Topical Gel, 2.5 Grams Single Use Unit

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*DATES OF INSPECTION

7/16/2024(Tue), 7/17/2024(Wed), 7/18/2024(Thu), 7/19/2024(Fri), 7/22/2024(Mon), 7/23/2024(Tue), 7/24/2024(Wed), 7/25/2024(Thu), 7/26/2024(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."