DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	10/28/2019-11/7/2019* FEI NUMBER 3004819860

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sherri C. Muncrief Merket, Pharmacist-in-Charge (PIC)

FIRM NAME	STREET ADDRESS
Abilene Nuclear LLC dba National Central Pharmacy	3402 S 14th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Abilene, TX 79605-4904	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 I OBSERVED:

OBSERVATION 1

Personnel engaging in aseptic processing was observed with exposed skin.

Specifically, your firm's pharmacy manager was observed during the production the non-patient specific sterile drug product, EPI-Shugarcaine Su/F Ophth 1 ml/vial, Rx (b) (6), as having his head, partially exposed facial skin, inside LAF Hood (b) (4)

OBSERVATION 2

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically, your pharmacy manager failed to adequately disinfect materials transferred from the ISO 7 Cleanroom into LAF Hood (b) (4) which was later used in the production of sterile drug products. For example, on 10/30/2019, I observed your pharmacy manager aseptically process the drug product for "Office Use Only", EPI-Shugarcaine Su/F Ophth 1 ml/vial, Rx (b) (6), (b) (4) 1-ml vials, Expiry 11/13/2019. While producing this lot of sterile drug product, I observed the following items were not disinfected prior to entering the ISO 5 LAF Hood (b) (4)

A. During setup for production, your pharmacy's manager failed to disinfect the tray containing ampules of Lidocaine 4% Pres-Free prior to entering the ISO 5 LAF hood. The ampules were removed from the non-disinfected tray and disinfected once inside the LAF hood.
B. Your firm's pharmacy manager was observed placing a non-disinfected "light green" plastic

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container used to hold the (b) (4) vials of finished sterile EPI-Shugarcaine Su/F Ophth 1 ml/vials into the ISO 5 LAF hood for the purpose of performing visual inspection of each vial quality.

OBSERVATION 3

Personnel touched equipment or other surfaces located outside of the ISO 5 classified aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.

Specifically, your firm pharmacy failed to disinfect sterile gloves prior to re-entry into ISO 5 LAF hood while aseptically processing the sterile drug product, EPI-Shugarcaine Su/F Ophth 1 ml/vial after collecting additional supplies in the ISO 7 Cleanroom too many times to count. At the completion of aseptic processing, I observed your firm's pharmacy manager pick paper off the floor, place it into the trashcan, and return into the ISO 5 LAF hood without disinfecting and or change the sterile gloves prior to re-entry into the ISO 5 area.

OBSERVATION 4

Personnel placed equipment/supplies in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically, your firm's pharmacy manager failed to place supplies in an area, which would not inhibit first pass airflow within LAF Hood (b) (4) during aseptic processing. For example, during the aseptic processing of the sterile drug product, EPI-Shugarcaine Su/F Ophth 1 ml/vial, Rx (b) (6), I observed empty/filled vials and Lidocaine 4% Pres-Free 4.5 mls ampules arranged in a manner that created a disruption in first pass airflow within the ISO 5 LAF hood.

OBSERVATION 5

The facility design was observed to allow the influx of poor quality air into a higher classified area.

Specifically, your firm failed to have adequate HEPA filter coverage in the prevention of poor quality

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air from entering into your ISO 7 Cleanroom, high quality air area. For example, your firm's cleanroom is designed with (b) (4) (b) (4) your firm's ISO 7 Cleanroom and non-classified radio-pharmaceutical inspection/ packaging/ shipping/ receiving/ cleaning area, which fails to have adequate HEPA filter coverage to ensure poor air quality does not enter into the ISO 7 Cleanroom. Additionally, your firm failed to include the (b) (4) as part of your firm's cleanroom (b) (4) recertification to verify air quality.

OBSERVATION 6

Disinfecting agents and cleaning pads or wipes used in the ISO 5 aseptic processing are not sterile.

Specifically, your firm is using the non-sterile cleaning product, (b) (4) within your firm's LAF Hood (b) (4) designated for the production of sterile drug product.

OBSERVATION 7

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worse-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your firm procedure, Media Fill Challenge, Document # 6.36, Change # 2, documents the use of a (b) (4) (b) (4) Your firm's PIC reported the manipulations and complexity performed using the kit is representative of those performed during radio-pharmaceutical drug processing. The same kit components were modified to simulates non-radio-pharma aseptic transfers that uses a (b) (4) (b) (4) manipulation into syringes. The simulated media fill fail to be representative of your firm's non-radio-pharma aseptic processing worse-case activities and conditionst.

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OBSERVATION 8

The batch production and control records are deficient in that they do not include identification of persons performing and checking each significant step in the operation.

Specifically, your firm's production worksheets failed to include a second verifier for critical steps of your pharmacy's production process. For example, during my review of the following selected production batch records, I found only your firm's pharmacist, who produced the drug product, was the only firm employee who reviewed and approved the production batch/lot. Your pharmacy failed to have a second person to verify defined critical steps within the production process that effect finished drug product identity, strength, quality, and purity.

A. Rx (b) (6), Cefuroxime 7.5mg/ml Ophth Soln 2.5 mls, Expiry 1/18/2019
B. Rx (b) (6), EPI-Shugarcaine Su/F Ophth 1 ml/vial, Expiry 11/13/2019
C. Rx (b) (6), Joint Mix Ropiv/Morph 10 mg, Expiry 10/10/2019
D. Rx (b) (6), Joint Mix # 2 Bupiv/Morph, Expiry 9/11/2019
E. RX (b) (6), HAB 1-0.5-25 per 0.2 ml Lipo, Expiry 1/21/2020

***DATES OF INSPECTION**
10/28/2019(Mon), 10/29/2019(Tue), 10/30/2019(Wed), 10/31/2019(Thu), 11/01/2019(Fri), 11/04/2019(Mon), 11/05/2019(Tue), 11/06/2019(Wed), 11/07/2019(Thu)

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