

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

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax: (404)253-1202	DATE(S) OF INSPECTION 8/19/2019-8/23/2019*
	FEI NUMBER 3012263025

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James T. Fanning IV, Pharmacy Manager

FIRM NAME East Marietta Drug Company	STREET ADDRESS 1480 Roswell Rd
CITY, STATE, ZIP CODE, COUNTRY Marietta, GA 30062-3670	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

You produced highly potent drugs without providing adequate cleaning of work surfaces to prevent cross-contamination.

Specifically, during observation of production on 08/19/19, we witnessed production of Bi-Est 3 mg/mL Cream (calculated lot #: 08192019@3) and did not witness cleaning of work surfaces prior to beginning production of the next drug product, T3 32.5 mcg/T4 175 mcg SR Capsules (calculated lot #: 08192019@2).


OBSERVATION 2

Personnel did not disinfect and change gloves frequently enough to prevent contamination.

Specifically, while observing production on 08/19/19, the technician informed us that she routinely sanitizes between each drug product and changes gloves. However, we observed production occurring with no glove change between 3 different drug products (Gabapentin 50mg Capsule Floor Stock Capsule, calculated lot# 08192019@4; Bi-Est 3mg/mL Cream, calculated lot# 08192019@3; T3 32.5 mcg/T4 175mcg SR Capsules, calculated lot#: 08192019@2). Moreover, I frequently observed the technician place or move personal eyeglasses or verify calculations on a personal cell phone while using gloved hands.

OBSERVATION 3

Non-microbial contamination was observed in your production area.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Johnetta F Walters, Investigator Gideon N Esuzor, Investigator		DATE ISSUED 8/23/2019

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<small>FIRM NAME</small> East Marietta Drug Company	<small>STREET ADDRESS</small> 1480 Roswell Rd	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Marietta, GA 30062-3670	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of Non-Sterile Drug Products	


Specifically, while observing production on 8/19/2019, the following were noted:

- Cobwebs in the vents right above the production area.
- Dust on top of the hood where some production operations occur.
- The sink used to wash critical production equipment was noticeably dirty.

On 8/19/2019, the following drug products were produced under these conditions: Calcitriol 17 ng/ml Almond Oil Liquid (Lot# 08192019@7); Gabapentin 50mg (Lot# 08192019@4); Bi-Est 3mg/ ml Cream (Lot# 08192019@3); and T3 32.5mcg/T4 175mcg SR Caps (Lot# 08192019@2).

***DATES OF INSPECTION**

8/19/2019(Mon), 8/20/2019(Tue), 8/23/2019(Fri)

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Johnetta F Walters, Investigator Gideon N Esuzor, Investigator		<small>DATE ISSUED</small> 8/23/2019
	(Empty space for additional notes or signatures)		