

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 404 BNA Drive BLDG 200, STE 500 Nashville, TN 37217 (615) 366-7801 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 11/06-07/18; 11/14/18
	FEI NUMBER 3003637491 -3011504027 BCH 11/24/18

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Jerry M. Duren, Owner

FIRM NAME Duren's Health Mart Pharmacy	STREET ADDRESS 215 Dexter L. Woods Memorial Blvd
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CITY, STATE AND ZIP CODE Waynesboro, TN 38485	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs
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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) (WE) OBSERVED:
Self 11/14/18

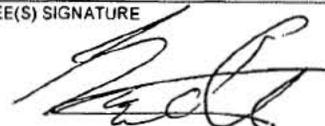
Observation I:

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically, expired bulk active pharmaceutical ingredients (APIs) were used in the production of drug products. Examples include but are not limited to the following:

- Estriol Vaginal Cream 0.5mg/ml (Rx (b) (6)) made/dispensed on 03/21/18; Bulk API lot # (b) (4) - EXP 03/05/2018
- Estriol Vaginal Cream 0.5mg/ml (Rx (b) (6)) made/dispensed on 09/06/18; Bulk API lot # (b) (4) - EXP 03/05/2018
- Domperidone 10mg Capsules (Rx (b) (6)) made/dispensed on 09/23/18; Bulk API lot # (b) (4) - EXP 11/30/2016
- Omeprazole 2mg/ml suspension (Rx (b) (6)) made/dispensed on 08/06/18; Bulk API lot # (b) (4) - EXP 02/2018
- Omeprazole 2mg/ml suspension (Rx (b) (6)) made/dispensed on 09/07/18; Bulk API lot # (b) (4) - EXP 02/2018

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Brandon C. Heitmeier, Investigator	DATE ISSUED 11/14/2018
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Nashville, TN 37217 (615) 366-7801

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TYPE OF ESTABLISHMENT INSPECTED

Producer of Non-Sterile Drugs

Observation 2:

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, hormone and non-hormone containing drug products are compounded under a (b) (4) hood without any gowning or controls in place to prevent cross-contamination by personnel between batches.

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Brandon C. Heitmeier, Investigator

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