

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

DISTRICT ADDRESS AND PHONE NUMBER

555 Winderley Place, Suite 200
Maitland, FL 32751
(407) 475-4700 Fax: (407) 475-4768
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

03/02/2015 - 03/04/2015

FEI NUMBER

3005758901

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Stephen A. Burklow, Owner and Pharmacist

FIRM NAME

Burklow Pharmacy, Inc.

STREET ADDRESS

4880 Woodbine Rd

CITY, STATE, ZIP CODE, COUNTRY

Pace, FL 32571

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 I OBSERVED:

OBSERVATION 1

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, your firm does not test non-sterile drug products for the presence of objectionable microorganisms prior to distribution

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, there are no established specifications for microbial limits for the non-sterile drug products prepared by your firm.

OBSERVATION 3

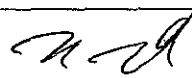
Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, your firm does not test each batch of finished drug product prior to distribution. For example, for the last 3 months your firm prepared non-sterile drug products, such as progesterone creams, testosterone capsules, and buprenorphine troches, and distributed them without testing to determine conformance with potency.

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Michael H. Tollon, Investigator



DATE ISSUED

03/04/2015