DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1
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, you stated your firm does not test finished drug products prior to distribution. For example, documentation states since 12/22/15 to the time of this inspection your firm prepared and distributed non-sterile drug products without testing to determine conformance with potency (topical and capsule products) and microbial limit specifications (topical products). Below are some examples:

A. Creams and gels containing one or more active pharmaceutical ingredients such as testosterone, estradiol, lidocaine HCl, and pentoxifylline.

B. Capsules containing ingredients such as progesterone and liothryronine sodium (T3).

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 topical drug products made by your firm.
OBSERVATION 3

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 topical preparations for presence of objectionable microorganisms prior to distribution.