

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 4040 N. Central Expressway, #300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 11/28/17-12/7/17
	FEI NUMBER 3005331940

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Kimberly J. Fontenot, Pharmacist-in-Charge

FIRM NAME Peoples Pharmacy, Inc.	STREET ADDRESS 3801-B S. Lamar Blvd.
CITY, STATE AND ZIP CODE Austin, TX 78704	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs

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:


OBSERVATION 1

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products. For example,

- a) Your firm uses water from a (b) (4) system for use in certain drug products whose formulation requires water. Your firm is also using the water from the (b) (4) system to make (b) (4) Water (b) (4) for use in certain drug products. Your firm has no documentation of testing performed (microbiological or analytical) to show the water at least/at minimum meets the specifications for Purified Water, USP. Examples of lots made using the (b) (4) water include lot #11-27-2017@32 of Clonidine (Dye Free/Flavor Free) 0.05mg/1mL Suspension and lot #11-13-2017@3 of Omeprazole (Grape/Marshmallow) Standard + 2mg/mL Suspension. Examples of products made using the (b) (4) Water made from the (b) (4) water include lot #11-12-2017@12 of Dexamethasone/Mupirocin/Amphotericin B ((b) (4)) 0.1%/100mg/10mg/60mL Nasal Spray and lot #06-15-2017@21 of Tranexamic Acid 5% Solution.
- b) Your firm uses Acetone CP grade for making drug products. The Acetone is labeled for "technical use only". In the past 6 months your firm has made (b) (4) lots of drug products using Acetone CP including (b) (4) (b) (4) of Squaric Acid Dibutyl Ester/Acetone 0.5% Solution and (b) (4) (b) (4) of Diphenylcyclopropenone 5% Solution.

OBSERVATION 2

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Margaret M. Annes, CSO	DATE ISSUED 12/07/2017
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4040 N. Central Expressway, #300
Dallas, TX 75204
214-253-5200

DATE(S) OF INSPECTION

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Peoples Pharmacy, Inc.

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3801-B S. Lamar Blvd.

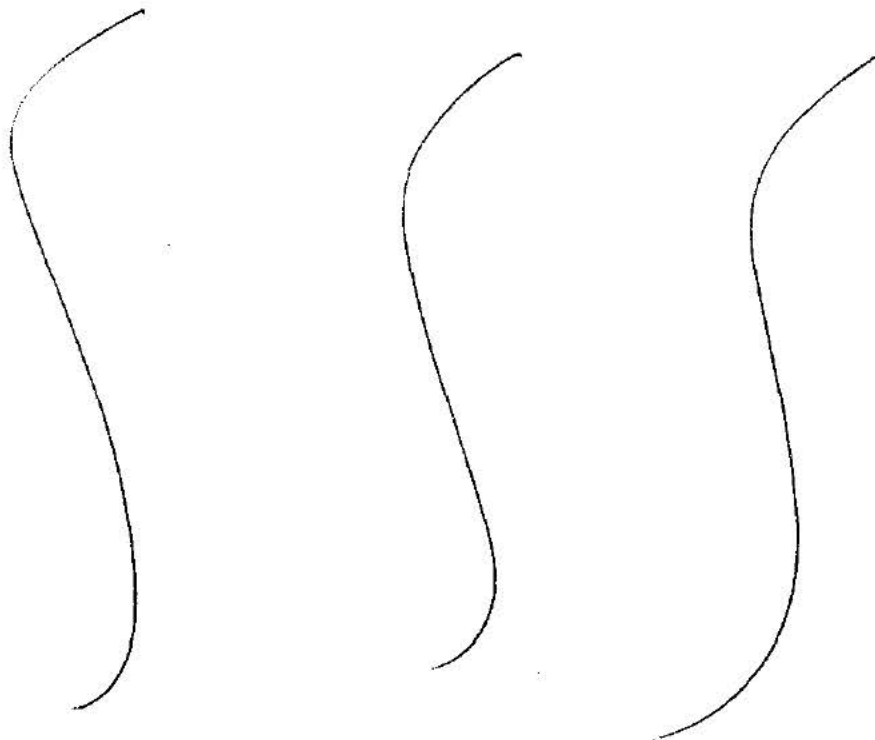
CITY, STATE AND ZIP CODE

Austin, TX 78704

TYPE OF ESTABLISHMENT INSPECTED

Producer of Non-Sterile Drugs

Specifically, I observed on 11/30/17 that the rubber spatulas used in the production of non-sterile drug products were discolored, cracked and damaged (unsmooth surface). There were several lots of different products made on the date including lot #11-30-2017@5 of Estradiol (E2)/Prog (P4) 0.5mg/100mg/GM Cream.



SEE
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OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Margaret M. Annes

EMPLOYEE(S) NAME AND TITLE (*Print or Type*)

Margaret M. Annes, CSO

DATE ISSUED

12/07/2017