

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

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| 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 11/29/17-12/7/17 |
| | FEI NUMBER 3003987288 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Samantha A. Tally, Pharmacist-in-Charge

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| FIRM NAME Peoples Pharmacy, Inc. | STREET ADDRESS 4018 N. Lamar Blvd. |
| CITY, STATE AND ZIP CODE Austin, TX 78756 | 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 (b) (4) water in certain drug products whose formulation requires water. Your firm is also using the (b) (4) water to make (b) (4) Water ((b) (4) for use in certain drug products. Your firm has no documentation of any testing performed (analytical or microbiological) to show the water at least/at minimum meets the specifications for Purified Water, USP. Examples of products made using the (b) (4) water include lot #09082017@10 of Clonidine (Grape Simple Syrup) 0.1mg/mL Suspension and lot #11012017@21 of Clonidine (Strawberry/Marshmallow Simple Syrup) 0.1 mg/mL Suspension. Examples of lots made using the (b) (4) Water made from the (b) (4) water include lot #11302017@33 of Tranexamic Acid 5% Solution and lot #11212017@32 of Dexamethasone/Gentamicin/Itraconazole 0.1%/80mg/100mg/30mL Nasal Spray.

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 made (b) (4) of drug product using the Acetone CP - lot #10062017@10 of Squaric Acid (In Acetone) 0.1% Solution.

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| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE <i>Margaret M. Annes</i> | EMPLOYEE(S) NAME AND TITLE (Print or Type) Margaret M. Annes, CSO | DATE ISSUED 12/07/2017 |
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