

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

DISTRICT ADDRESS AND PHONE NUMBER 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax: (425) 302-0404	DATE(S) OF INSPECTION 10/30/2017-11/21/2017* FEI NUMBER 3012086997
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Devin R. Trone, Pharm. D. , Co-Owner

FIRM NAME Trone Health Services, Inc.	STREET ADDRESS 2790 W Cherry Ln Ste 100
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CITY, STATE, ZIP CODE, COUNTRY Meridian, ID 83642-1102	TYPE ESTABLISHMENT INSPECTED Producer of non-sterile drug products
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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 WE OBSERVED:
OBSERVATION 1

Non-pharmaceutical grade components are used in the formation of non-sterile drug products.
Specifically,

Your firm has not conducted any testing (microbial and analytical) of the water generated through (b) (4) (b) (4). This water has been used as a component during the production of various drug products.
For example:

A. RX (b) (6), (b) (7)(C) 100 gm Dental Gel Anesth-L-10% T-4% P-10%, lot 08242017@7 with the label direction for use "APPLY SMALL AMOUNT TO AFFECTED AREA(S) PRIOR TO PROCEDURES".

B. RX (b) (6), (b) (7)(C) 480 mL Xylitol/ESG Oral Rinse, lot 08042017@6.

***DATES OF INSPECTION**
10/30/2017(Mon), 10/31/2017(Tue), 11/02/2017(Thu), 11/09/2017(Thu), 11/13/2017(Mon), 11/17/2017(Fri), 11/21/2017(Tue)

X Kenneth O Gee
Investigator
Signed By: 2001873861
Date Signed: 11-21-2017 19:21:05

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tracy K Li, Investigator Kenneth O Gee, Investigator	DATE ISSUED 11/21/2017
	Tracy K Li Investigator Signed By: 2000061590 Date Signed: 11-21-2017 19:18:46 X	