

**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 6/27/2016-7/15/2016*
	FEI NUMBER 3012086997

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Devin R. Trone , 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 sterile and non-sterile drugs
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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**

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, you did not produce sterile drugs under ISO 5 conditions. All manipulations performed in the production of drug products, listed below which are required to be sterile are conducted in an unclassified enclosure, AirClean Systems PowderSafe™ 700 series Ductless Balance Enclosure located in an ISO 8 production laboratory. The interior top underside of this enclosure contained residue build-up and yellow stains. There are no controls to prevent microbial contamination, bacterial endotoxin and unintended chemical and physical contaminants for producing sterile drug products.

- Acetylcysteine Ophthalmic 10% Solution
- Gentamicin Irrigation Solution 80 MG/60 ML Solution

**OBSERVATION 2**

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

A. There is no stability data to demonstrate it is suitable to use expired Active Pharmaceutical Ingredients (APIs) and components in the production of drug products. In addition, drug products with expired APIs and components were assigned Beyond Use Dates (BUDs) and/or Discard After dates that exceeded that of the API or component.

1. DHEA E4M 6MG for prescription (b)(6),(b)(7)(C), Discard After date 12/25/16 was produced on

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- 6/29/16 from a lot of expired DHEA (b) (4) , lot (b) (4) ; Expiration 6/21/16.
2. Acetylcysteine Ophthalmic 10% Solution, lot 05212015@4 has BUD 6/20/15; Discard After date 9/12/16 was produced on 5/21/15 with the below components:
- Acetylcysteine (b) (4) lot (b) (4); Expiration date 11/30/2014.
  - (b) (4) lot and expiration date not recorded.
3. Testosterone Cypionate Sesame 200 MG/GM Injectable, lot 11122015@2, BUD 2/10/16 was produced on 11/13/15 with (b) (4) lot (b) (4) , Expiration date 10/30/15.
4. Baclofen 20 MG/ML Oral Suspension, lot 12022014@10, BUD 1/1/15, Discard After date 3/26/16 was produced on 12/2/14 with the following components:
- (b) (4) ; lot (b) (4) ; Expiration 11/30/07.
  - (b) (4) (b) (4) ; lot (b) (4) ; Expiration date 11/18/14.
5. Dream Cream (A/L-A/S/T) Cream, lot 02242016@11, BUD 5/24/16 was produced on 2/24/16 with (b) (4) lot (b) (4), Expiration date 2/16/16.

B. There is no stability data to explain inconsistency between the BUD and "Discard After" date for several of your drug products produced at your facility to ensure finish products have acceptable potency, purity, quality and characteristics.

1. Acetylcysteine Ophthalmic 10% Solution, lot 05092016@19, BUD 6/8/16 has Discard After date 9/1/17.
2. Buprenorphine 06. MG/ML Injection Solution for veterinary use, lot 11172015@16, BUD 12/17/15 has Discard After date 2/15/16.
3. Baclofen 20 MG/ML Oral Suspension, lot 10262015@27, BUD 11/25/15 has Discard After date 2/17/17.

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**OBSERVATION 3**

Control procedures fail to include adequacy of mixing to assure uniformity and homogeneity.

Specifically, your firm does not have data to support the adequacy of your blending process for encapsulated drug products. The processing of DHEA CR 6 MG Capsule, lot 06282016@13 consisted of adding coloring, Riboflavin USP to API and excipient in a mortar and pestle. This (b) (4) mixture is manually mixed until the coloring appears to have evenly dispersed. There is no assurance that a homogeneous mixture is achieved. In addition, your firm does not perform potency testing on this product. The most recent potency testing for a similar product, DHEA 10 MG/CAP was done 5/15/09.

**OBSERVATION 4**

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, analytical testing including potency testing was not performed on baclofen suspension identified in MedWatch report 11801434. Potency testing was never done on any baclofen containing drug products. In addition, no analytical testing was ever done to determine finished product potency for several of your drug products including the top three non-sterile drug products produced at your facility from 3/1/16 to 6/25/16, listed below.

- A. Progesterone E4M 100 MG produced for (b) (4) prescriptions
- B. Progesterone 200 MG/GM Versa produced for (b) (4) prescriptions
- C. Estriol 2 MG/GM Versabase Cream produced for (b) (4) prescriptions

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**OBSERVATION 5**

Written records are not made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically, the firm failed to adequately conduct and document investigations regarding the use of the API Baclofen in the production of prescription drug products which had been recalled by two of their suppliers for different reasons:

A. Attix Pharmaceuticals API Baclofen USP, lot 131009 in powdered form was used in the production of at least (b) (4) prescriptions/lots from 4/9/14 and 10/9/15 including but not limited to baclofen suspension and baclofen topical cream lots 04092014@13, 08182014@2, 12222014@13, 02022015@22, 04092015@10, 09222015@8, 10092015@2. The firm received a recall letter from Attix Pharmaceuticals faxed to them on 3/25/15 stating that all lots of all pre-packaged products were being recalled for possible exposure to penicillin products since January 5, 2012. According to the Pharmacist, the firm pulled the API Baclofen, lot 131009 from their inventory but they did not document the quantity on hand nor the amount and date of the destruction of the lot by their third-party contractor Guarantee Returns. They did not conduct an investigation into what prescription drug products were produced from API Baclofen, lot 131009 and whether to notify physicians and/or patients of the risks or to have the drug products returned and destroyed.

B. Medisca API Baclofen USP, lot 125184/C in powdered form, manufactured by Taizhou Xinyou Pharmaceutical & Chemical Co., Ltd., was used in the production of (b) (4) prescriptions/lots between 10/12/15 and 12/23/15 including but not limited to baclofen suspension and baclofen topical cream lots 10122015@5, 10262015@27 and 12232015@7. According to the pharmacist, the firm pulled a partial (b) (4) bottle (actual quantity unknown) from their shelf after receiving the Medisca recall notification which was faxed to them on 12/23/15 indicating the product was being recalled for possible endotoxins and microorganisms. Lot 125184/C was used to manufacture the baclofen suspension identified in MedWatch report 11801434, however the firm did not document their investigation into this drug product for super potency. Additionally, the firm did not document their

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investigation of any other batches using the recalled lot of Baclofen.

**OBSERVATION 6**

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

Specifically, a piece of non-contact surface cabinetry with peeling paint and exposed partial board was observed directly above dishwasher racks holding glassware and utensils that were cleaned with soap and water from the production of Methimazole 5 MG/ML Suspension and DHEA 6 MG Capsule. The area of exposed partial board is not an easily cleanable surface and the moisture from the dishwasher may lead to the potential for microbial growth and degradation.

**\*DATES OF INSPECTION**

6/27/2016(Mon),6/28/2016(Tue),6/29/2016(Wed),6/30/2016(Thu),7/01/2016(Fri),7/15/2016(Fri)

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