

**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

8/23/2021-8/27/2021

FEI NUMBER

1000107122

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Kristen Adams, RPh, Pharmacy Co-Owner, Treasurer

FIRM NAME

Chastains Inc. dba Owl Tri State  
Pharmacy

STREET ADDRESS

1275 Highland Ave

CITY, STATE, ZIP CODE, COUNTRY

Clarkston, WA 99403-2846

TYPE ESTABLISHMENT INSPECTED

Producer of Non-Sterile Drug Products

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 OBSERVED:**

**OBSERVATION 1**

Non-microbial contamination was observed in your production area.

Specifically,

a. Glassware beakers and mortars that were considered clean and stored in the clean glassware shelves were dirty, had grease, or corrosion stains. Dirty glassware was observed to be used for non-hazard and USP-800 hazardous drug production.

b. An air vent and ceiling grids above the entrance to the USP-800 lab and non-hazard lab, and above the (b) (4) dispenser machine had large pieces of dust hanging. This was right in front of the two compounding labs. The top of the (b) (4) dispenser machine was covered with copious amounts of dust.

c. (b) (4) sinks in the pharmacy area and (b) (4) in each production lab had corrosion stains. The linoleum floor around the sink of the non-hazard lab was heavily soiled and had open gaps where it was not sealed closed to the wall.

**SEE REVERSE  
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Roger F Zabinski, Investigator - Dedicated  
Drug Cadre

DATE ISSUED

8/27/2021

Roger F Zabinski  
Investigator - Dedicated Drug  
Cadre  
Signed By: Roger F. Zabinski -S  
Date Signed: 08-27-2021  
1:22:29

X

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d. Some apparent chemical residue was observed around the base of the (b) (4) hood in the non-hazard lab and around the analytical balance. The residue was observed visually and with the use of a UV light.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Roger F Zabinski, Investigator - Dedicated Drug Cadre	<small>Roger F Zabinski Investigator - Dedicated Drug Cadre Signed By: Roger F. Zabinski -S Date Signed: 08-27-2021 1:22:29</small> X _____	DATE ISSUED 8/27/2021

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."