

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 404 BNA Dr., Bldg. 200, Suite 500 Nashville, TN 37217 615-366-7801 ORAPharm2_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 02/10, 11 & 13/2020
	FEI NUMBER 3015826061

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Douglas E. Clark, Pharmacist

FIRM NAME Blount Discount Pharmacy, Inc.	STREET ADDRESS 129 Gill St.
CITY, STATE AND ZIP CODE Alcoa, TN 37701	TYPE OF ESTABLISHMENT INSPECTED Non-sterile Drug Product Producer

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

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

Specifically, I observed built-up residue on the scale, stained and nicked spatulas, scratched and cloudy glassware used to produce non-sterile drug products. You use these same utensils and equipment to manufacture hazardous drugs and non-hazardous types of drugs including but not limited to hormone, Fluorouracil, and opioid products.

Observation #2

Agents used for cleaning the laminar flow hood and other equipment between products do not include a deactivating agent (e.g. oxidizing agent) to prevent cross-contamination.

Specifically, the cleaning agents I observed used between batches for equipment and the hood were (b) (4) and dish soap only.

Observation #3

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

Specifically, you use Sodium Hyaluronate, (b) (4) and (b) (4) as components in hormone creams, cough syrup and suspensions. You do not have adequate documentation to demonstrate these components meet suitability for use in non-sterile drug products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Claire M. Minden Investigator	DATE ISSUED 02/13/2020
	<small>Digitally signed by Claire M. Minden -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300178102, cn=Claire M. Minden -S Date: 2020.02.13 10:19:25 -06'00'</small>		