

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

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	DATE(S) OF INSPECTION 7/8/2019-7/12/2019* FEI NUMBER 3015119302
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Deepa (NMI) Jacob, Pharmacist In Charge

FIRM NAME Keystone Rx LLC	STREET ADDRESS 3070 Bristol Pike, Building 2, Suite 216-b
CITY, STATE, ZIP CODE, COUNTRY Bensalem, PA 19020-5364	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 WE OBSERVED:
OBSERVATION 1**

Non-microbial contamination was observed in your production area.

Specifically, on July 9, 2019, after producing Rx (b) (6), 5% Flurbiprofen/ 2% Cyclobenzaprine/ 5% Lidocaine cream, and subsequent cleaning, the following were observed:

- A) Apparent dried powder residue in the front grate of the biological safety cabinet (hood). There were approximately six grate holes observed with yellow residue near the scale inside the hood, approximately three grate holes observed with white residue, and approximately another four grate holes observed with yellow residue.
- B) Apparent white powder residue remained on the hood's processing surface. We observed Flurbiprofen powder spillage during weighing operations for Rx (b) (6).
- C) Smear residue remained immediately in front of the grate.
- D) Yellow staining remained on scale (b) (4) located inside the hood. The scale is used to weigh raw materials for production.

***DATES OF INSPECTION**

7/08/2019(Mon), 7/09/2019(Tue), 7/12/2019(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Sena G Dissmeyer, Investigator David A Oluwo, Investigator	Sena G Dissmeyer Investigator Signed by: Sena G. Dissmeyer-IS Date Signed: 07-12-2019 10:33:14 X	DATE ISSUED 7/12/2019

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X David A Oluwo
Investigator
Signed By: 2001987776
Date Signed: 07-12-2019 10:33:56

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Sena G Dissmeyer, Investigator David A Oluwo, Investigator	<p align="center">Sena G Dissmeyer Investigator Signed By: Sena G. Dissmeyer -S Date Signed: 07-12-2019 10:33:14</p> <p align="center">X</p>	DATE ISSUED 7/12/2019