

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax: (404)253-1202	DATE(S) OF INSPECTION 2/21/2017-3/7/2017* FEI NUMBER 3005471681
---	--

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher N. Thomas , Pharmacist

FIRM NAME Partners In Care, Inc.	STREET ADDRESS 2551 Limestone Pkwy, Suite 2
CITY, STATE, ZIP CODE, COUNTRY Gainesville, GA 30501	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

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

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, non-sterile wipes are used to clean drug components prior to placing them in the ISO 5 Laminar Flow Hood. In addition, the wipes used to clean the ISO 5 Laminar Flow Hood are also not sterile.

***DATES OF INSPECTION**

2/21/2017(Tue),2/22/2017(Wed),2/27/2017(Mon),2/28/2017(Tue),3/07/2017(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tamara J Henderson, Investigator	DATE ISSUED 3/7/2017
	☒ Tamara J Henderson Tamara J Henderson Investigator Signed for Tamara Henderson-C	