

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 10/2/2019-10/8/2019*
	FEI NUMBER 3009422393

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Russell L. Funk, CEO

FIRM NAME Banner Pharmacy Services, LLC	STREET ADDRESS 7300 W Detroit St
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CITY, STATE, ZIP CODE, COUNTRY Chandler, AZ 85226-2410	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products
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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 I OBSERVED:

OBSERVATION 1

Disinfecting agents and used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

Per SOP 02-04.02 "Cleaning and Disinfecting of the Sterile Compounding Area" cleaning agents used in the ISO classified work areas are described as an "(b) (4)" or "(b) (4)" " however, during review of the cleaning agent "(b) (4)", it was confirmed the agent is not sterile.

***DATES OF INSPECTION**

10/02/2019(Wed), 10/03/2019(Thu), 10/04/2019(Fri), 10/08/2019(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Bryan L Mcguckin, Investigator	Bryan L. Mcguckin Investigator Signed by: Bryan L. Mcguckin -S Date Signed: 10-08-2019 10:58:37 X _____	DATE ISSUED 10/8/2019