

**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 3/20/2017-3/24/2017
	FEI NUMBER 3011630209

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
William A. Stuart, RPh , President

FIRM NAME Hartley Medical Center Pharmacy, Incorporated	STREET ADDRESS 113 W Victoria St
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CITY, STATE, ZIP CODE, COUNTRY Long Beach, CA 90805-2162	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)** Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically,

The repeater pump used to dispense drug stocks into smaller unit vials is wheeled from the ISO-7 Ante room to the ISO-6 IV Clean Room when needed and wheeled back to the Ante room when not needed.

**Observation 2)** The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically,

I observed that gaps in the emergency exit double doors from the ISO-6 IV room are sealed with tape, but there were some areas where the tape had been worn or was not fully maintaining the seal, thus possibly compromising the integrity of the ISO-6 room.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Roger F Zabinski, Investigator	DATE ISSUED 3/24/2017
		<input checked="" type="checkbox"/> Roger F Zabinski Roger F Zabinski Investigator Signed by: Roger F. Zabinski-S