

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314		DATE(S) OF INSPECTION 3/5/2019-3/12/2019* FEI NUMBER 3011624368
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Kimberly I. Young, Director of Operations		
FIRM NAME Option Care Enterprises, Inc. dba Option Care	STREET ADDRESS 9601 Baptist Health Dr., Ste 330	
CITY, STATE, ZIP CODE, COUNTRY Little Rock, AR 72205-6325	TYPE ESTABLISHMENT INSPECTED Producer of sterile drugs	
<p>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.</p>		
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1</p> <p>Materials or supplies were not disinfected prior to entering the aseptic processing areas.</p> <p>Specifically, on 03/05/19, I observed two operators place (b) (4) in ISO 5 hoods^{(b) (4)} and^{(b) (4)} without wiping with (b) (4) sterile (b) (4) during the production of Milrinone 60mg, Rx (b) (6) and TPN 3:1, Rx (b) (6) respectively.</p>		
<p>OBSERVATION 2</p> <p>Your facility design allowed the influx of poor quality air into a higher classified area.</p> <p>Specifically, on 03/05/19, I observed the door from the non-classified area to the ISO 7 ante room open at the same time the door from the ISO 7 ante room to the ISO 7 (b) (4). This occurred during the production of Vancomycin HCL, Rx (b) (6) Milrinone 60mg, Rx (b) (6) and TPN 3:1, Rx (b) (6)</p>		
<p>OBSERVATION 3</p> <p>Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jennifer L. Huntington, Investigator	DATE ISSUED 3/12/2019
		Jennifer L. Huntington Investigator Signed By: Jennifer L. Huntington X Date Signed: 03-12-2019 09:11:50
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<p>Specifically, media fills are not representative of the maximum batch size for aseptic operations for syringes and IV bags. For example, your firm produced (b) (4) syringes of (b) (4) Rx (b) (6) on 12/12/18, however your media fill consists of (b) (4) vials, (b) (4) syringes, and (b) (4) IV bag.</p>			
<p>*DATES OF INSPECTION 3/05/2019(Tue), 3/06/2019(Wed), 3/07/2019(Thu), 3/08/2019(Fri), 3/12/2019(Tue)</p>			
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