

**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

9/1/2016-9/14/2016\*

FEI NUMBER

3010166765

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mark G. Winters , Chief Operating Officer and Vice-President of Operations

FIRM NAME

Healix Infusion Therapy, Inc.

STREET ADDRESS

1075 W Park One Dr Ste 200

CITY, STATE, ZIP CODE, COUNTRY

Sugar Land, TX 77478-2576

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.

Your firm utilizes several different disinfectants in the ISO 5 areas of which two, **(b) (4)** and **(b) (4)** are non-sterile.

**\*DATES OF INSPECTION**

9/01/2016(Thu),9/02/2016(Fri),9/07/2016(Wed),9/09/2016(Fri),9/14/2016(Wed)

**SEE REVERSE  
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Stephen D Brown, Investigator



9/14/2016

DATE ISSUED

9/14/2016

Stephen D Brown  
Stephen D Brown  
Investigator  
Signed by: Stephen D. Brown-S