DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Dallas District Office 4040 North Central Expressway, Suite 400 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	5/12-16/14
	FEI NUMBER 3010166765

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mark G. Winters, COO & Executive Vice President of Operations

FIRM NAME	STREET ADDRESS
Healix Infusion Therapy, Inc.	1075 W. Park One Drive, Suite 200
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sugar Land, TX 77478	Outsourcing Facility

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) (WE) OBSERVED:

1. Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

a) Your firm is not performing environmental monitoring of the ISO 5 compounding area every day that your firm is preparing injectable drug products. Your procedure, 103-05.01 Viable and Non-Viable Air Sampling dated 3/31/14, states that "Viable and Non-Viable Air Sampling will be performed (b) (4) internally and at least (b) (4) ".

SOP 103-06.01 Surface Sampling Procedure dated 3/31/14, does not specify a frequency for obtaining surface samples. Your firm is currently performing surface samples (b) (4) from various sites in the ISO 5, ISO 7 and ISO 8 classified areas.

Your firm has produced sterile drug products on all days from (b) (4) . On 5/12/14, your firm produced lot #s 6947-0 of Morphine 25mg/25mL in 0.9% Sodium Chloride (syringe); 6954-0 of Promethazine 12.5mg/25mL in 0.9% Sodium Chloride (25mL bag); 6955-0 of Promethazine 25mg added to 0.9% Sodium Chloride (50mL bag); 6953-0 of Ondansetron 16mg added to 0.9% Sodium Chloride (50mL bag); 6951-0 of Neostigmine 5mg/5mL (syringe); and 6948-0 of Neostigmine 5mg/10mL (syringe).

b) Your firm is not monitoring the gloves of each operator working in the ISO 5 area and ISO 7 clean room each day that sterile drug products are prepared. SOP 103-08.01 Gloved Fingertip Sampling dated 3/31/14, does not specify the frequency of sampling of gloves. Your firm is currently sampling the fingertips of operators (b) (4) .

2. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Margaret M. Annes Darla Ann Taylor	Margaret M. Annes, CSO Darla J. Christopher, CSO Dorcus Ann Taylor, CSO	05/16/2014

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Dallas District Office 4040 North Central Expressway, Suite 400 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	5/12-16/14
	FEI NUMBER 3010166765

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mark G. Winters, COO & Executive Vice President of Operations

FIRM NAME	STREET ADDRESS
Healix Infusion Therapy, Inc.	1075 W. Park One Drive, Suite 200
CITY, STATE AND ZIP CODE Sugar Land, TX 77478	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

established.

Specifically, media fills performed by your firm with each of the operators that work in the ISO 5 area do not closely simulate actual production conditions or cover worst case or most challenging conditions. A (b) (4) Media Fill performed on 3/28/14 that entailed filling a (b) (4) bag was performed by two of the (b) (4) pharmacists that can work in the ISO 5 area and one of the (b) (4) technicians. A (b) (4) Media Fill performed on 2/25/14 that entailed filling (b) (4) syringes was performed by one of the (b) (4) pharmacists that can work in the ISO 5 area and four of the (b) (4) technicians. Your written procedures, SOP 103-07.01 Personnel Aseptic Media Fill Verification dated 3/31/14 and SOP 103-22.01 (b) (4) Verification dated 03/14, do not require that all personnel working in the ISO 5/ISO 7 area producing sterile drug products perform these media fills and do not define a frequency for when they should be performed. All (b) (4) technicians and three of the pharmacists have performed a media fill using a (b) (4) Validation Kit that does not closely simulate actual production conditions or cover worst case or most challenging conditions such as operator fatigue and batch size. For example, the maximum time an operator can be filling a batch is (b) (4). The time to complete the (b) (4) is 1/2 hour. Batch sizes can be up to (b) (4) syringes and (b) (4) bags depending on the type of compounding performed and the order. The (b) (4) covers (b) (4) different manipulatons or processes (one example for each type).

3. Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform.

Specifically, the general gowning attire for entry into the ISO 5/ISO 7 classified areas allows operators to use safety glasses or some other type of eyeglasses. On 5/12/14 we observed one operator working in the ISO 5/ISO 7 cleanroom wearing reading glasses and the other wearing safety glasses that were not flush with (b) (6) face. The general gowning requirements allowed exposed skin around the eyes and forehead of the person preparing the sterile drug product. On 5/12/14 your firm produced lot #s 6947-0 of Morphine 25mg/25mL in 0.9% Sodium Chloride (syringe), 6954-0 of Promethazine 12.5mg/25mL in 0.9% Sodium Chloride (25mL bag), 6955-0 of Promethazine 25mg added to 0.9% Sodium Chloride (50mL bag), 6953-0 of Ondansetron 16mg added to 0.9% Sodium Chloride (50mL bag), 6951-0 of Neostigmine 5mg/5mL (syringe), and 6948-0 of Neostigmine 5mg/10mL (syringe).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Margaret M. Annes Darla Ann Taylor	Margaret M. Annes, CSO Darla J. Christopher, CSO Dorcus Ann Taylor, CSO	05/16/2014