DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration 4040 North Central Expressway Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	11/10/10; 11/29-30;12/2-3, 6-9/10
	FEI NUMBER 3000717703

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Bruce W. Bagley, Center Manager

FIRM NAME	STREET ADDRESS
Pharmedium Services LLC	12620 West Airport Blvd. #130
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sugar Land, TX 77478-6200	Outsourcing Pharmacy

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. Review of complaints for the period between 3/2010 and the present revealed that your firm had received approximately 11 complaints for various Compounded Sterile Preparations (CSP's) containing Heparin related to subpotency and/or lack of therapeutic effect.

In some instances, the complaint investigation included a copy of a certificate of analysis issued by the contract laboratory responsible for relevant potency testing associated with each CSP. The certificate of analysis, in each case, documented that the contract laboratory had conducted a potency test for Heparin using an (b) (4) . In each case, the certificate of analysis indicated that the lot passed testing for potency.

However, your firm lacked data to demonstrate that the (b) (4) used by your contract laboratory meets or exceeds the requirement in the official compendium (e.g. Factor IIa testing).

Some examples of the complaints in question consist of the following:

A. A complaint dated 11/8/2010 which documented a lack of therapeutic effect for the CSP, "Heparin 25,000 Units added to 0.45% Sodium Chloride Injection (100 units/ml), lot #101029800022

B. A complaint dated 7/7/2010 which documented that the CSP, "Heparin 25,000 Units added to 5% Dextrose Injection USP (50 units/ml) 500ml Bag", lot #101018200053 was subpotent.

C. A complaint dated 5/17/2010 which documented a lack of therapeutic effect associated with the CSP, "Heparin 25,000 Units added to 5% Dextrose Injection (50 units/ml), lot #101007800068.

2. Your firm does not maintain an approved master compounding record which documents the concentration range determination for compounded heparin service admixtures.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Stephen D. Brown	Stephen D. Brown, Investigator	12/09/2010

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For example, the document entitled, "(b) (4) Compounded Heparin Service Admixture" dated 11/26/10 documents, in part, that the (b) (4)) There is no documentation to indicate that this calculation is part of an approved release specification which is used in the calculation of potency.

3. SOP #CPS-707 entitled, "Microbiological and Environmental Testing" (Effective date: 6/16/10) documents, in part, that a Microbiological Action Report will be issued for any microbial excursion in the Class 100 hood which exceeds the action limit of (b) (4) . Review of your "ID Tracking Log" for the Sugar Land site for 2010 revealed contamination in Hood # (b) (4) (Date: 7/7/10, (b) (4)) which was 3 CFU. There was no documentation that a Microbiological Action report had been issued or that an appropriate investigation had been conducted.

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		Stephen D. Brown, Investigator	12/09/2010