DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food & Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	03/17/2026-03/19/2026
	FEI NUMBER 1910218

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Desiree L. McCaslen, Site Manager

FIRM NAME	STREET ADDRESS
BioChem Sioux City, Inc.	5500 1/2 Bradley St.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sioux City, IA 51111	Heparin Sodium Crude Manufacture

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:

LABORATORY SYSTEM

1. The firm has not established an ongoing stability program for heparin sodium crude (b) (4) to support the assigned (b) (4) expiration date. For example, the firm provided only one stability report from 2018 (Ref.: SRS-STAB 2017-014, art. no. 44.538.300, authorized 14 Feb 2018), with no subsequent stability studies conducted through March 2026.

2. The firm follows procedure AMB-101355, BioChem WI: Heparin Sodium (b) (4) Assay, version 7.0, effective 16 Jul 2024, a modified method that has not been validated. For example, the firm has used this same modified method for approximately 15-20 years. Furthermore, the method is used release (b) (4) lots of heparin sodium crude from (b) (4) within expiration date.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Carolina D. Vasquez -S Digitally signed by Carolina D. Vasquez -S Date: 2026.03.19 12:18:05 -07'00'	Carolina D. Vasquez, Investigator	03/19/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."