DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Denver District Office 6th Ave. & Kipling St.-Bldg. 20 DFC Denver, CO 80225 Industry Information: www.fda.gov/oc/industry	06/14,15,16,19,20,21/2011
	FEI NUMBER 3005231248

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Brian J. McCudden, Vice President, API Strategy & Boulder Operations

FIRM NAME	STREET ADDRESS
Hospira Boulder, Inc.	4876 Sterling Dr.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Boulder, Colorado 80301	Active Pharmaceutical Ingredient Manufacturer

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.The firm has released product without the documentation of a robust process that yields a high degree of assurance in the performance of the manufacturing process.

Specifically,
a) Carboplatin Batches #A-3800-09-0011R, A-3800-09-0012R, A-3800-09-0013R, A-3800-09-0014R, A-3800-10-0001, A-3800-10-0005, A-3800-10-0006, A-3800-11-0001, A-3800-11-0002, A-3800-11-0003, A-3800-11-0004, A-3800-11-0005, A-3800-11-0006, A-3800-11-0007, A-3800-10-0004R1, A-3800-10-0005R1, A-3800-10-0006R1, A-3800-10-0007R1, A-3800-10-0008R1, and A-3800-10-0009R1 were released without a validated process.

b) Carboplatin Batches #A-3800-11-0001, A-3800-11-0002, A-3800-11-0003, A-3800-11-0004, A-3800-11-0005, A-3800-11-0006, A-3800-11-0007, A-3800-10-0005R1, A-3800-10-0006R1, and A-3800-11-0009R1 were released without a validated process and were not put on a stability testing schedule.

c) The first batch, Carboplatin Batch #A-3800-11-0008, that was released under a concurrent validation process, (b) (4) documented nineteen redline changes to the batch record (excluding changes that required additional sampling instructions, the addition of operator personal protective equipment, or operator error notations). These changes deviated from the approved validation protocol.

2. Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,
During a walk-through of your facility on 06/14/11, a build up of white powder residue was observed on the metal rim of where the isolator glove attaches to the (b) (4) in processing room (b) (4). The glove box is used to dry (b) (4) Your shift manager stated the gloves

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	K Beaubaert-Hoefen Erika V. Butler	Kimberley A. Hoefen Zachery L. Miller Erika V. Butler	06/21/2011

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are only removed if there is a tear in the glove, "otherwise they stay on". In addittion, Standard Operating Procedure A-MFE-0058 Rev. 11, titled (b) (4) is deficient because it does not address cleaning the metal rims of the isolator glovebox for which the gloves are attached.

3. Written procedures are not established for the cleaning of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,
Validation of procedures for cleaning equipment that are used interchangeably between active pharmaceutical ingredients has not been completed. Active pharmaceutical ingredients manufactured at your facility include, but not limited to; Carboplatin, Paclitaxel, Tromethamine, and Pamidronic Acid. Furthermore, the cleaning batch record AA050 Rev. 6, titled; Post-Campaign Cleaning; which is used for product to product cleaning verification is deficient because it does not specify: 1. Tools used for cleaning 2. The dissasembly of the bottom filter plate of the filter dryer (equipment (b) (4) for cleaning underneath. 3. Detailed manual vessel scrub procedures and locations.

4. Lack of adequate written procedures for obtaining a homogeneous raw material sampling.

Specifically,
The firm's sampling procedure, Sampling and Dispositioning Raw Materials (U-QCG-0008, Rev. 17, Effective Date 4/28/2011), lacks the details necessary to provide an employee instruction in collecting a homogeneous sample of raw materials (i.e. which part of the container to sample).

5. The firm did not follow their Standard Operating Procedures.

Specifically,
a) A-MFC-0003, Rev. 8, Equipment Cleaning and Use Log, states:
(b) (4)

(b) (4) On 06/14/2011, it was noted that Rooms (b) (4) had Equipment Cleaning and Use Logbooks that dated back to as early as 2009 without documented MFG

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Supervisor/Designee review.

b) U-QCA-0001, Rev. 18, Sample Submission and Sample Tracking Procedures, states:

(b) (4) It was noted on 06/15/2011, that 5 (b) (4) of sample entries logged into the Sample Submission Logbook were observed to be incomplete.

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