DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax: (913) 495-5115 Industry Information: www.fda.gov/oc/industry	07/29/2013 - 08/16/2013* FEI NUMBER 1925262 SG 8/16/2013 JBA

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Andrew F. Knudten, Vice President, Operations

FIRM NAME	STREET ADDRESS
Hospira, Inc.	1776 North Centennial Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
McPherson, KS 67460	Sterile Drug 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 WE OBSERVED:

OBSERVATION 1

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning significant chemical, physical, or other change or deterioration in a distributed drug product.

Specifically,

A. NDA-Field Alerts were not submitted within three working days of glass particulate complaints for the following sterile lyophilized drug products filled on line (b)(4)

1) 12/13/12 Complaint 1531844 and 04/05/13 Complaint 1668113 for Erythrocin Lactobionate for I.V., 500mg per vial, 10mL vial, lot 201153A
2) 12/13/12 Complaint 1531848 and 02/15/13 Complaint 1606380 for Erythrocin Lactobionate for I.V., 500mg per vial, lot 201053A
3) 03/18/13 Complaint 1641529 for Vancomycin Hydrochloride for injection USP 500mg, 10mL vial, lot 213453A
4) 05/13/13 Complaint 1716083 for Vancomycin Hydrochloride for injection USP 500mg, 100mL vial, lot 260653A
5) 05/28/13 Complaint 1736523 for Vancomycin Hydrochloride for injection USP 500mg, 100mL vial, lot 270253A
6) 07/01/13 Complaint 1788050 for Erythrocin Lactobionate for I.V., 500mg per vial, lot 222403A
7) 12/07/12 Complaint 1526014 Vecuranium Bromide for Injection USP, 500mg, 10mL vial, lot 211553A.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shirley J. Berryman, Investigator Shirley J. Berryman Janet B. Abt, Investigator Janet B. Abt	08/16/2013

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OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

A. Your investigations of confirmed complaints of glass particulate in sterile lyophilized drug products have not been timely.

1) Timely investigations related to glass particulate complaints were not provided to the sponsor of (b) (4) mg Lyophilized sterile drug product lots (b) (4) and (b) (4).
   a. Complaint registration date of 04/25/13, sample received 05/20/13 for Complaint 1693899 lot (b) (4) Plant completed investigation and proposed verbiage was forwarded to the sponsor on 06/24/13.
   b. Complaint registration date of 06/25/13, sample received 07/08/13 for Complaint 1776963 lot (b) (4) Plant sent email with summary to the sponsor on 08/06/13.
   c. Complaint registration date of 07/10/13, sample received 07/15/13 for Complaint 1800932 lot (b) (4) Plant investigation was completed on 08/09/13.

2) A Drug Medical Assessment was not initiated until 07/23/2013 and signed 07/31/2013 for Erythromycin, Vancomycin, Vecuronium Bromide and (b) (4) drug products.

B. The 100% visual inspection after lyophilization form (identified as "Light Test for (b) (4) Lyophilized Products" in batch production records) fails to define what type of particulate noted during the 100% visual inspection. The Light Test form has the defect as only: "Particulate". The lack of identification of what type of particulate will not allow an adequate investigation of complaints related to glass particulate. You received complaints of glass particulate in the following lots and only the number of defects was recorded.

1) Batch record (b) (4) for (b) (4) mg, 10mL vial documents 1 defect for particulate
2) Batch record 201053A for Erythromycin documents 2 defects for particulate
3) Batch record 222403A for Erythromycin documents 1 defect for particulate
4) Batch record 201153A for Erythromycin documents 1 defect for particulate

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OBSERVATION 3

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

A. There is a failure to classify glass particulate as a Critical defect since there is a potential for causing adverse health consequences. Your procedure SOP No. QC0820.00, Addendum A, Sampling and Auditing of Light Inspected Product classifies glass particle as a Major A defect instead of Critical defect which would likely result in serious adverse health consequences.

B. Your operators' visual inspection for Lyophilized drug product qualification program does not include examples of glass particulate in vials for training purposes.

* DATES OF INSPECTION:
07/29/2013(Mon), 07/30/2013(Tue), 07/31/2013(Wed), 08/01/2013(Thu), 08/02/2013(Fri), 08/06/2013(Tue), 08/07/2013(Wed), 08/08/2013(Thu), 08/09/2013(Fri), 08/13/2013(Tue), 08/15/2013(Thu), 08/16/2013(Fri)

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