DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	08/16/2010 - 08/31/2010* FEI NUMBER 1818977

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: J. Donald Ferry, General Manager

FIRM NAME	STREET ADDRESS
JHP Pharmaceuticals, LLC	870 Parkdale Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rochester, MI 48307-1740	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

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,

(A) On 8/05/10, production personnel noticed foreign material on the grate covering (b) (4) HEPA filter in the ceiling of bulk formulation room (b) (4) during set-up operations. Further inspection by management revealed the material was also on the HEPA filter and filter housing. Laboratory analysis identified the material as (b) (4), the active pharmaceutical ingredient in (b) (4) and (b) (4), with a total estimated quantity of approximately 200 mg. Additionally, there are no written procedures for cleaning and inspection of such (b) (4) HEPA filtered supply air outlets. Products formulated under open processing conditions in room (b) (4) include (b) (4) lot (b) (4) manufactured (b) (4) 0 (exp (b) (4)), (b) (4) lot (b) (4) manufactured (b) (4) (exp (b) (4)), and (b) (4) lot (b) (4) manufactured (b) (4) (exp (b) (4)).

(B) On 8/09/10, foreign material was found within (b) (4) HEPA filtered supply air outlet in the ceiling of bulk formulation room (b) (4) as part of an ongoing investigation. Laboratory analysis identified the material as (b) (4), the active pharmaceutical ingredient in (b) (4), with a total estimated quantity of approximately 40 mg. Additionally, there are no written procedures for cleaning and inspection of such (b) (4) HEPA filtered supply air outlets. Products formulated under open processing conditions in room (b) (4) include (b) (4) lot (b) (4) manufactured (b) (4) (exp (b) (4)), (b) (4) lot (b) (4) manufactured (b) (4) (exp (b) (4)), and (b) (4) lot (b) (4) manufactured (b) (4) (exp (b) (4)).

OBSERVATION 2

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, product (b) (4) equipment is not of suitable design to prevent product (b) (4) within the area from the (b) (4) valve during (b) (4). Ongoing investigation 10-08-012 identifies (b) (4) equipment, such as the (b) (4) used during the (b) (4) as a contributing root cause of the gancyclovir found on and within the supply air outlet in the ceiling of bulk formation room (b) (4) due to occasional product (b) (4) from

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jeffrey D. Meng, Investigator Michele L. Forster, Investigator	08/31/2010

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the (b) (4) valve during (b) (4).

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

(A) Prior to 8/23/10, there were no written procedures for handling product (b) (4) that are less than 500 ml. On 8/05/10, an estimated total quantity of approximately 200 mg of (b) (4) was found on and within the (b) (4) HEPA-filtered supply air outlet in the ceiling of bulk formulation room (b) (4). On 8/09/10, an estimated total quantity of approximately 40 mg of (b) (4) was found within a supply air outlet in the ceiling of bulk formulation room (b) (4). Ongoing investigation 10-08-012 identifies product (b) (4) as a contributing cause of the drug product residues found on and/or in such supply air outlets.

(B) SOP-QLA-MQA-03010-RO "Quality Systems" pertaining to quality room hold procedures does not define the specific activities suspended when a room is on hold status. On 8/05/10, the Quality Unit placed room (b) (4) on hold from all activities pending further investigation into the foreign material ((b) (4)) found on the supply air outlet. The Hold for Disposition Form placed on room (b) (4) at approximately 5:00 PM was unclear regarding specific activities permitted while on hold status, and a complete cleaning of this room was performed at approximately 7:00 PM while the room was still on hold.

(C) SOP-MAN-GEN-03111-RO "Logbooks for Usage, Maintenance, and Cleaning (LUMAC)" (effective 3/10/10) states "Cleaning performed and signed for on another checklist shall be indicated in the events field of the LUMAC." However, (b) (4) ceiling cleanings implemented 3/31/10 that were documented on the sanitation schedule have not been recorded in the LUMAC for rooms (b) (4) and (b) (4).

*** DATES OF INSPECTION:**
08/16/2010(Mon), 08/17/2010(Tue), 08/18/2010(Wed), 08/24/2010(Tue), 08/27/2010(Fri), 08/31/2010(Tue)

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