DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	2/5/2018-2/23/2018* FEI NUMBER 3012746140

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Daniel T. Martins, Vice President Outsourcing Facility Services

FIRM NAME	STREET ADDRESS
Pentec Health	9 Creek Pkwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Boothwyn, PA 19061-3148	Outsourcing Facility

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

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, monitoring of temperature, humidity, and differential pressures for the ISO classified rooms is limited to facilities personnel reportedly performing visual checks of a (b) (4)-system screen running in the background on their desktop computers and responding only to alarms; and review of that data is not documented unless there is an alarm. SOP OF.014 V00, (b) (4) (b) (4), describes only storage temperatures; there is no mention of temperature, humidity, and differential pressures for any ISO classified rooms, and there are no requirements for review of that data during processing. There are no procedures that describe monitoring the temperature, humidity, and differential pressures in the ISO 5 (b) (4) during processing; monitoring is limited to performing a (b) (4) Test (b) (4), and responding to alarms. The ISO 5 (b) (4) is a standalone unit; it is not monitored via the (b) (4) system.

OBSERVATION 2

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, the temperature, humidity, and differential pressures that occur during processing in the cleanrooms and in the ISO 5 (b) (4) are not reviewed as part of batch release. In addition, the data for the temperature, humidity, and differential pressures in the cleanrooms and in the (b) (4) are not

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lisa B Orr, Investigator Christina K Theodorou, Investigator X Lisa B Orr Investigator Signed By: 2001685580 Date Signed: 02-23-2018 09:00:20	2/23/2018

maintained as part of the batch records. For example, there is no documentation that the temperature, humidity, and differential pressures in the cleanrooms and in the (b) (4) were reviewed for the release of Vancomycin HCl Stock Solution Injection Batch number (b) (4).

OBSERVATION 3

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

Specifically, the qualification of the (b) (4) does not include assessment of viable air and surface samples. The protocols did not specify viable testing was to be done, the executed protocols do not include viable testing data, and the summary reports do not discuss viable data results. Additionally, there is no record to indicate the certification activities performed by the firm were acceptable to meet the reported ISO-5 conditions.

OBSERVATION 4

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, the firm has not completed any studies or assessed any data to establish how long batches of Vancomycin HCl Stock Solution Injection or Magnesium Sulfate Heptahydrate Stock Solution Injection can be held before sterile (b) (4) and before filling. These processes use non-sterile API. There is no measurement of the microbial counts in (b) (4) solution and there are no established limits for the maximum microbial count before the limits of the (b) (4) could be exceeded. In addition, the media fill simulations did not assess the lengths of time that may be encountered before (b) (4).

OBSERVATION 5

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

Specifically, the SOPs do not include which utensils can be put into the washer or into the (b) (4); the washer SOP does not describe how to load equipment/utensils including which basket is appropriate;

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and the (b) (4) SOP does not describe the maximum load or how to (b) (4) equipment or utensils before placing them into the (b) (4) .

***DATES OF INSPECTION**

2/05/2018(Mon), 2/06/2018(Tue), 2/07/2018(Wed), 2/08/2018(Thu), 2/09/2018(Fri), 2/12/2018(Mon), 2/13/2018(Tue), 2/14/2018(Wed), 2/15/2018(Thu), 2/16/2018(Fri), 2/21/2018(Wed), 2/23/2018(Fri)

X Christina K Theodorou
Investigator
Signed By: Christina K. Theodorou -S
Date Signed: 02-23-2018 09:01:01

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lisa B Orr, Investigator Christina K Theodorou, Investigator X Lisa B Orr Investigator Signed By: 2001655590 Date Signed: 02-23-2018 09:00:20	2/23/2018