

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969	DATE(S) OF INSPECTION 11/13/2017-11/30/2017*
	FEI NUMBER 3013931875

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Michael Rutkowski, Vice President and General Manager

FIRM NAME QuVa Pharma, Inc.	STREET ADDRESS 519 State Route 173
CITY, STATE, ZIP CODE, COUNTRY Bloomsbury, NJ 08804-4047	TYPE ESTABLISHMENT INSPECTED 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**

Written procedures for sanitation are not followed.

Specifically, no cleaning was performed as per SOP NJ-SOP-SA-0003, Section 4.4, which states "(b) (4) cleaning of the Aseptic Processing Areas (cleanrooms and gowning/ante-rooms) should occur (b) (4) (b) (4) is used for production activities". However, Heparin 1unit/mL 3L Bulk, Lot (b) (4) compounding date 10/25/17 was not documented in the (b) (4) cleaning log for ISO-7 cleanroom (b) (4)

**OBSERVATION 2**

The batch production and control records are deficient in that they are not an accurate reproduction of the appropriate master production or control record and checked for accuracy, dated, and signed.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Tonia F Bernard, Investigator Zakaria I Ganiyu, Investigator	Tonia F Bernard Investigator Signed By: 2001637553 Date Signed: 11-30-2017 06:43:49 X	DATE ISSUED 11/30/2017

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969	DATE(S) OF INSPECTION 11/13/2017-11/30/2017*
	FEI NUMBER 3013931875

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Michael Rutkowski, Vice President and General Manager

FIRM NAME QuVa Pharma, Inc.	STREET ADDRESS 519 State Route 173
CITY, STATE, ZIP CODE, COUNTRY Bloomsbury, NJ 08804-4047	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Specifically, the (b) (4) noted in step 8 of the approved batch record for Heparin 1unit/mL 3L Bulk, Lot (b) (4), compounded on 11/06/17, states to “(b) (4) with (b) (4).” However, there was no documentation in the batch record to justify that (b) (4) was used for the (b) (4), not (b) (4). This lot was approved and released by Quality on 11/15/17 for further packaging into individually dosed syringes at your Sugar Land, TX facility.

**\*DATES OF INSPECTION**

11/13/2017(Mon), 11/14/2017(Tue), 11/15/2017(Wed), 11/16/2017(Thu), 11/17/2017(Fri), 11/21/2017(Tue), 11/30/2017(Thu)

X Zakaria I Ganiyu  
Investigator  
Signed By: Zakaria I. Ganiyu -S  
Date Signed: 11-30-2017 08:45:41

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Tonia F Bernard, Investigator Zakaria I Ganiyu, Investigator	Tonia F Bernard Investigator Signed By: 2001637553 Date Signed: 11-30-2017 08:43:49 X	DATE ISSUED 11/30/2017