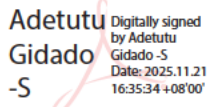


| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>FOOD AND DRUG ADMINISTRATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                               |                                                                            |                                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| DISTRICT ADDRESS AND PHONE NUMBER<br>12420 Parklawn Drive<br>Room 2032 Rockville, MD 20857<br>Phone: (301) 796-3334 Fax: (301) 847-8738<br>Email: <a href="mailto:CDER-OC-OMQ-Intemational483Response@fda.hhs.gov">CDER-OC-OMQ-Intemational483Response@fda.hhs.gov</a><br>Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>                                                                                                                                                                                                                                                                                                        |                                                                                                               | DATE(S) OF INSPECTION<br>11/17/2025-11/21/2025<br>FEI NUMBER<br>3006259537 |                                                                                     |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED<br>Mr. Shang Qinghai, General Manager                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                               |                                                                            |                                                                                     |
| FIRM NAME<br>HEC Pharm Co. Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                               | STREET ADDRESS<br>2 Binjiang Road                                          |                                                                                     |
| CITY, STATE, ZIP CODE, COUNTRY<br>Yidu, Hubei 443300 CN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                               | TYPE ESTABLISHMENT INSPECTED<br>API Manufacturer                           |                                                                                     |
| <p>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.</p>                                                 |                                                                                                               |                                                                            |                                                                                     |
| <p><b>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</b><br/> <i>The following observations pertain to the Active Pharmaceutical Ingredients (APIs) manufactured at your site for the US market.</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                               |                                                                            |                                                                                     |
| <p><b>OBSERVATION 1</b><br/> <b>Analytical method used for determination of impurities in API is inadequately validated.</b></p> <p>Specifically, the impurity method used for determination or quantification of impurities in (b) (4) Active Pharmaceutical Ingredient (API) did not detect the presence of an unknown impurity (b) (4) in the test sample solution. On 02/20/2025, OOT (b) (4) was initiated for assay OOT for (b) (4) batch# (b) (4). During the investigation, an unknown peak was detected in the assay chromatogram, which had not been detected in the impurity test chromatogram.</p>                                                              |                                                                                                               |                                                                            |                                                                                     |
| <p><b>OBSERVATION 2</b><br/> <b>Laboratory instruments are inadequately qualified for their intended use.</b></p> <p>Specifically, the Ultra High Performance Liquid Chromatography-Mass Spectrometer (UHPLC-MS) used for determination (b) (4) impurities in (b) (4) API has not been fully qualified for its intended use. Although, the installation, operation and performance qualification of the instrument was performed in July 2025 and the instrument has been used for method validation and release testing since August 2025, the MassLynx software used for data analysis and processing has not been qualified to ensure data integrity and compliance.</p> |                                                                                                               |                                                                            |                                                                                     |
| <p><b>OBSERVATION 3</b><br/> <b>The culture media (b) (4) used for microbial enumeration and environmental monitoring is not validated or adequately validated to determine its capability to support the growth of specific microorganisms.</b></p> <p>Specifically, growth promotion testing was not performed on the culture media used for surface microbial monitoring in the (b) (4) laboratories. In addition, (b) (4) water was used for</p>                                                                                                                                                                                                                        |                                                                                                               |                                                                            |                                                                                     |
| SEE REVERSE<br>OF THIS PAGE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | EMPLOYEE(S) SIGNATURE<br>Adetutu M Gidado, Investigator                                                       |                                                                            | DATE ISSUED<br>11/21/2025                                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <br>Adetutu Gidado<br>-S |                                                                            | Digitally signed<br>by Adetutu<br>Gidado -S<br>Date: 2025.11.21<br>16:35:34 +08'00' |

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

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DATE(S) OF INSPECTION

11/17/2025-11/21/2025

FEI NUMBER

3006259537

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Shang Qinghai, General Manager

FIRM NAME

HEC Pharm Co. Ltd.

STREET ADDRESS

2 Binjiang Road

CITY, STATE, ZIP CODE, COUNTRY

Yidu, Hubei 443300 CN

TYPE ESTABLISHMENT INSPECTED

API Manufacturer

growth promotion test performed on the (b) (4) used to evaluate foreign microorganism in the (b) (4) within the (b) (4) in-process testing (IPC) room.

**OBSERVATION 4**

**Manufacturing equipment are not maintained to prevent malfunctions.**

Specifically, on 11/17/2025 continuous leakage of liquid material was observed from the (b) (4) used during the (b) (4) step for (b) (4). Although the leakage was attributed to high operating, no corrective actions were taken to address the issue.

**OBSERVATION 5**

**Manufacturing computer and or related system is not adequately qualified for their intended use.**

Specifically, the distributed control system (DCS) software used to automate and monitor the operation the (b) (4) production process system did not detect that a valve was open during manufacturing, which led to partial product loss for (b) (4) batch# (b) (4).

**\*DATES OF INSPECTION**

11/17/2025 (Mon), 11/18/2025 (Tue), 11/19/2025 (Wed), 11/20/2025 (Thu), 11/21/2025 (Fri).

**SEE REVERSE  
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Adetutu M Gidado, Investigator

Adetutu  
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Digitally signed  
by Adetutu  
Gidado -S  
Date:  
2025.11.21  
16:35:11 +08'00'

DATE ISSUED

11/21/2025