DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Boulevard, 3rd Floor Parsippany, NJ 07054 (973) 331-4900	11/5/2024-11/8/2024; 11/12-11/15/2024; 11/18/2024
	FEI NUMBER 3033132864

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Michael Curry, Vice President of Operations	
FIRM NAME Empower Clinic Services New Jersey, LLC	STREET ADDRESS 203 Windsor Center Drive, Suite A16
CITY, STATE, ZIP CODE, COUNTRY East Windsor, NJ 08520-1410	TYPE ESTABLISHMENT INSPECTED Contract Testing Laboratory and Human Drug Compounding 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.

OBSERVATION 1
Written procedures are not reviewed and approved by the quality control unit.

Specifically,

Your firm failed to review and approve numerous SOPs which were drafted, reviewed, and approved by another firm prior to your firm's establishment in April 2024. Your firm has adopted these procedures, and they are being used for CGMP activities. The following are some examples of these SOPs written and approved by another firm, which you are currently using without review or approval by your firm:

Standard Operating Procedure	Name	Effective Date
EU-QA-GEN-043.00	Responsibilities of Quality Unit	02/29/2024
EU-QA-GEN-003.00	Reporting and Monitoring of Process Non-Conformance (Deviations)	01/10/2024
EU-QA-GEN-022.00	Corrective And Preventive Actions (CAPA)	01/23/2024
EU-QC-GEN-080.00	Handling of Out of Trend Results in the Quality Control Laboratory	01/16/2024
EU-VA-GEN-004.00	Qualification Procedure	05/23/2023
EU-QC-GEN-079.00	Handling of Lab Events In Quality Control Laboratory	05/23/2023
EU-QC-GEN-076.01	Handling and Qualification of Reference Standards	06/11/2024

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brandy N. Lepage Digitally signed by Brandy N. Lepage -S Date: 2024.11.18 19:11:59 -05'00' Anthony Donato -S Digitally signed by Anthony Donato -S Date: 2024.11.18 19:05:14 -05'00'	11/18/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Boulevard, 3rd Floor Parsippany, NJ 07054 (973) 331-4900	11/5/2024-11/8/2024; 11/12-11/15/2024; 11/18/2024
	FEI NUMBER 3033132864

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Michael Curry, Vice President of Operations	
FIRM NAME Empower Clinic Services New Jersey, LLC	STREET ADDRESS 203 Windsor Center Drive, Suite A16
CITY, STATE, ZIP CODE, COUNTRY East Windsor, NJ 08520-1410	TYPE ESTABLISHMENT INSPECTED Contract Testing Laboratory and Human Drug Compounding Outsourcing Facility

OBSERVATION 2

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

Your firm utilizes your (b) (4) system and the (b) (4) system to produce (b) (4) that is used for analytical and microbial drug product testing, and to produce sterile injectable and parenteral drug products. The (b) (4) system feeds the (b) (4) it produces into the (b) (4) system where (b) (4) (b) (4) is (b) (4) The (b) (4) system and the (b) (4) system qualifications transpired between 10/2020-05/**2024 and** 02/2021 to 05/2024, and are documented in the reports titled "Summary Report of Performance Qualification (Phase (b) (4) for (b) (4) Storage and Distribution System" PQ-(b) (4) U3-002.20.02, dated 09/27/2024 and "Summary Report of Performance Qualification of (b) (4) Phase (b) (4) (Line (b) (4))" PQ-(b) (4) U3-003.20.00, dated 06/17/2024; however, the (b) (4) systems were qualified without performing documented investigations into the following OOS that occurred during the qualification:

- OOS Investigation # M/NJ/OOS/02/01- this investigation was initiated following an OOS for TAMC of (b) (4) cfu/100 mL (specification: (b) (4) fu/100mL) on (b) (4) sample # (b) (4) collected from the (b) (4) system. The bacterial species identified from the colonies of growth was *Herbaspirillum hutiense* (gram negative, pathogenic).
- OOS Investigation # M/NJ/OOS/02/22/02- this investigation was initiated following an OOS for TAMC of TNTC (too numerous to count) (specification: (b) (4) cfu/mL) on (b) (4) sample # (b) (4) collected from the (b) (4) system. The bacterial species identified from the colonies of growth was *Ralstonia insidiosa* (gram negative, pathogenic).
- OOS Investigation # M/03/00S/04/22/01- this investigation was initiated following an OOS for TAMC of TNTC (too numerous to count) (specification: (b) (4) cfu/mL) on (b) (4) samples # (b) (4) (b) (4) collected from the (b) (4) system. The bacterial species identified from the colonies of growth was *Burkholderia cepacia* (gram negative, pathogenic).
- OOS Investigation # M/NJ/OOS/07/23/01- (07/18/2023) this investigation was initiated following an OOS for TAMC of TNTC (too numerous to count) (specification: (b) (4) cfu/mL) on (b) (4) samples # (b) (4) (b) (4) collected from the (b) (4) system. The bacterial species identified from the colonies of growth were *Burkholderia cepacia* (gram negative, pathogenic) and *Ralstonia insidiosa* (gram negative, pathogenic).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brandy N. Lepage -S Digitally signed by Brandy N. Lepage -S Date: 2024.11.18 19:12:24 -05'00' Anthony Donato -S Digitally signed by Anthony Donato -S Date: 2024.11.18 19:05:39 -05'00'	11/18/2024

- OOS Investigation # M/NJ/OOS/08/23/03- (08/16/2023) this investigation was initiated following an OOS for TAMC of TNTC (too numerous to count) (specification: (b) (4) cfu/mL) on (b) (4) samples # (b) (4) (b) (4) collected from the (b) (4) system. The bacterial species identified from the colonies of growth were *Burkholderia cepacia* (gram negative, pathogenic) and *Ralstonia insidiosa* (gram negative, pathogenic).
- OOS Investigation # M/NJ/OOS/08/23/05- (08/21/2023) this investigation was initiated following an OOS for TAMC of TNTC (too numerous to count) (specification: (b) (4) cfu/mL) on (b) (4) samples # (b) (4) (b) (4) collected from the (b) (4) system. The bacterial species identified from the colonies of growth were *Burkholderia cepacia* (gram negative, pathogenic) and *Ralstonia insidiosa* (gram negative, pathogenic).
- OOS Investigation # M/NJ/OOS/08/23/06- (08/22/2023) this investigation was initiated following an OOS for TAMC of TNTC (too numerous to count) (specification: (b) (4) cfu/mL) on (b) (4) samples # (b) (4) (b) (4) collected from the (b) (4) system. The bacterial species identified from the colonies of growth was *Burkholderia cepacia* (gram negative, pathogenic) and *Ralstonia insidiosa* (gram negative, pathogenic).

Succeeding the qualification of the (b) (4) system OOS Investigation # M/NJ/OOS/07/24/02 (07/29/24) was initiated following an OOS for BET in the (b) (4) sample # (b) (4) EU/mL (specification: (b) (4) EU/mL). The investigation failed to include corrective and preventative actions to help mitigate the ongoing gram negative bacterial contamination within the (b) (4) system: Additionally, since 01/01/2024 the following microbial identification of colony isolates from (b) (4) and (b) (4) samples were not investigated:

a) There was a total of 49 pathogenic bacteria colonies that were isolated and identified from samples collected from the (b) (4) system (Equipment ID: MF-(b) (4)-018), between 01/01/2014-11/15/2024, which includes *Ralstonia insidiosa*, *Burkholderia vietnamiensis*, *Burkholderia cenocepacia*, *Burkholderia cepacia*. The Quality Unit did not formally investigate the source of the contaminates that persisted in the (b) (4) system, and/or institute corrective and preventative actions to address the issue.

b) There was a total of 401 pathogenic bacteria colonies that were isolated and identified from samples collected from the (b) (4) system (Equipment ID: MF(b) (4)-016) between 01/01/2014-11/15/2024, which includes *Burkholderia anthina*, *Burkholderia cenocepacia*, *Burkholderia cepacia*, *Burkholderia lata*, *Burkholderia metallica*, *Burkholderia vietnamiensis*, *Herbaspirillum huttiense*, *Paenibacillus glucanolyticus*, and *Ralstonia insidiosa*. The Quality Unit did not formally investigate the

source of the contaminates that persisted in the (b) (4) system, and/or institute corrective and preventative actions to address the issue.

OBSERVATION 3

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

Specifically, your quality unit failed to follow SOP EU-VA-GEN-004.00, Qualification Procedure, Effective Date: 23-MAY-2023, in that, you failed to perform performance qualification (PQ) for any of your High-Performance Liquid Chromatography (HPLC), Ultra-Performance Liquid Chromatography (UPLC), and Ultraviolet (UV) Spectrophotometer instruments used for release and stability testing (assay and impurity testing) for drug products such as (b) (4) Injection in (b) (4) mg/(b) (4) mL (b) (4) mg (b) (4) mL); (b) (4) Injection (b) (4) mg/(b) (4) mL (b) (4) mg/mL); and (b) (4) Injection (b) (4) mg/vial.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity.

Specifically,

A. Your firm has not performed a method suitability for the compendial (USP) method <71> "Sterility Tests" and has not performed a method verification study for the compendial method <788> "Particulate Matter in Injections" (Method 1 Light Obscuration Particle Count Test), which are tests utilized in the stability testing of the drug product (b) (4) Injection (b) (4) mg (b) (4) mL (b) (4) mg/mL), as indicated in the standard test procedure titled "Standard Test Procedure: Product Name: (b) (4) Injection (b) (4) mg/(b) (4) mL (b) (4) mg/mL)" STP-DP-003.02. (b) (4) Injection (b) (4) mg (b) (4) mL (b) (4) mg/mL), lots # (b) (4) (b) (4) were tested in 05/2024, 06/2024, and 09/2024.

B. Your firm has not completed method transfer studies for the transferred stability study test procedure titled "Standard Test Procedure: Product Name: (b) (4) Injection (b) (4) mg (b) (4) mL (b) (4) mg/mL)" STP-DP-003.02, which is utilized for the stability testing of the (b) (4) drug product (b) (4) Injection (b) (4) mg (b) (4) mL (b) (4) mg/mL). (b) (4) Injection (b) (4) mg (b) (4) mL (b) (4) mg/mL), lots # (b) (4) (b) (4) were tested in 05/2024, 06/2024, and 09/2024.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Boulevard, 3rd Floor Parsippany, NJ 07054 (973) 331-4900	11/5/2024-11/8/2024; 11/12-11/15/2024; 11/18/2024
	FEI NUMBER 3033132864

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Michael Curry, Vice President of Operations	
FIRM NAME Empower Clinic Services New Jersey, LLC	STREET ADDRESS 203 Windsor Center Drive, Suite A16
CITY, STATE, ZIP CODE, COUNTRY East Windsor, NJ 08520-1410	TYPE ESTABLISHMENT INSPECTED Contract Testing Laboratory and Human Drug Compounding Outsourcing Facility

C. Your firm has not completed a method suitability study for the USP compendial procedure <71> "Sterility Tests," which is utilized in the stability testing of the drug product (b) (4) Injection, per standard test method titled "Standard Test Procedure: (b) (4) Injection in (b) (4) mg/(b) (4) mL (b) (4) mg (b) (4) mL)" STP-DP-002.00. (b) (4) Injection lot #(b) (4) was tested for sterility by your firm in 05/2024.

D. Your firm has not completed a method transfer study prior to use of the transferred test procedure titled, "Standard Test Procedure: Product Name: (b) (4) Injection (b) (4) mg/vial" STP-DP-014.02, which is utilized for the stability testing of drug product (b) (4) Injection (b) (4) mg/vial. (b) (4) Injection (b) (4) mg/vial, lot #'s (b) (4), were tested by this method in 05/2024.

E. The stability protocol titled "Stability Study Protocol for Drug Product: Product Name: (b) (4) Injection (b) (4) mg (b) (4) mL (b) (4) mg/mL)", STP-QC-0022.00, was used for the stability testing of (b) (4) Injection mg mL mg/mL), lot #'s (b) (4) for the T=12-month timepoint, in 09/2024. The protocol indicates that sterility testing, and bacterial endotoxin are required tests; however, your firm did not perform these tests on the aforementioned drug product stability samples.

F. The microbiology laboratory is using (b) (4) containers to dilute, test, and collect (b) (4) samples for BET, according to the procedure titled "Sampling and Analysis of (b) (4) EU-MB-GEN-003.00, without appropriate studies to determine that the container composition does not interfere (i.e., absorb) with endotoxin recovery and lead to false negative laboratory test results.

G. Your firm has not completed a method verification for the compendial method <85> "Bacterial Endotoxins," which is utilized to test the (b) (4) samples that are used in QC analytical, and microbiology testing of drug products. Additionally, the (b) (4) is a component in drug product production.

OBSERVATION 5

Appropriate controls are not exercised over computers or related systems to assure that changes in the master production and control records or other records are instituted only by authorized personnel.

Specifically,

A. The Quality Unit does not perform periodic audit trail reviews of the electronic data generated in the analytical and microbial testing of drug products. Audit trails are not monitored on the data acquisition software LabSolutions UV-Vis" for the UV Spectrophotometer (Equipment ID: QC-UVIS-022) and SamplerSight Pharma for the Particle Measuring System (Equipment ID: QC-PAMS-073). The UV Spectrophotometer is utilized for the stability

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Boulevard, 3rd Floor Parsippany, NJ 07054 (973) 331-4900	11/5/2024-11/8/2024; 11/12-11/15/2024; 11/18/2024
	FEI NUMBER 3033132864

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Michael Curry, Vice President of Operations	
FIRM NAME Empower Clinic Services New Jersey, LLC	STREET ADDRESS 203 Windsor Center Drive, Suite A16
CITY, STATE, ZIP CODE, COUNTRY East Windsor, NJ 08520-1410	TYPE ESTABLISHMENT INSPECTED Contract Testing Laboratory and Human Drug Compounding Outsourcing Facility

testing for (b) (4) Injection in (b) (4) mg(b) (4) mL(b) (4) mg(b) (4) mL), and the (b) (4) drug product (b) (4) Injection (b) (4) mg(b) (4) mL(b) (4) mg/mL).

B. The data server utilized to store drug product testing information is shared with a non-affiliated pharmaceutical company that has a separate FEI number. The outside pharmaceutical company has administrator access to the drug product raw testing data and audit trails within the Empower Waters™ Empower® 3 software that is used for HPLC and GC analysis on the(b) (4) HPLC, (b) (4) GC, and (b) (4) UPLC instruments in the QC analytical laboratory. Additionally, the outside pharmaceutical company has access to the data generated on the MALDI Biotyper Sirius, used for microbial colony identification, the Endosafe Nexgen-MCS, which is utilized for bacterial endotoxin testing on drug product samples, and the Scanstation 300 utilized to scan and photograph (b) (4) plates.

C. The Waters™ Empower® 3 data acquisition software processing methods that are utilized to analyze the drug products (b) (4) Injection in (b) (4) mg(b) (4) mL(b) (4) mg(b) (4) mL), (b) (4) Injection (b) (4) mg/vial, and the(b) (4) product (b) (4) Injection(b) (4) mg/(b) (4) mL ((b) (4) mg/mL) are not locked according to QC Manager. The analysts can modify the processing method used for analysis.

OBSERVATON 6
Deviations from written test procedures are not recorded and justified.

Specifically, the HPLC injection sequence delineated in the analytical test procedure STP-DP-003.02, titled "Standard Test Procedure: Product Name: (b) (4) Injection(b) (4) mg(b) (4) mL(b) (4) mg/mL)" and the standard operating procedure, "System Suitability Testing" EU-QC-GEN-071.00 was not followed for the assay and related substance testing of the t=9M stability testing of (b) (4) Injection (b) (4) mg(b) (4) mL(b) (4) mg/mL). The following are some examples:

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Boulevard, 3rd Floor Parsippany, NJ 07054 (973) 331-4900	11/5/2024-11/8/2024; 11/12-11/15/2024; 11/18/2024
	FEI NUMBER 3033132864

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael Curry, Vice President of Operations

FIRM NAME	STREET ADDRESS
Empower Clinic Services New Jersey, LLC	203 Windsor Center Drive, Suite A16
CITY, STATE, ZIP CODE, COUNTRY East Windsor, NJ 08520-1410	TYPE ESTABLISHMENT INSPECTED Contract Testing Laboratory and Human Drug Compounding Outsourcing Facility

Drug Product	Lot #	Testing	Standard Test Procedure Requirement	Actual Test Procedures Performed
(b) (4) Injection (b) (4) mg (b) (4) mL (b) (4) mg/mL)	(b) (4)	Assay (5/29/2024) *Run aborted after 1st System Suitability Injection	Column Saturation (at least (b) (4) flow rate (b) (4) mL/min)	Column Saturation set tc (b) (4) in processing method, and does not appear to be run (i.e., no injection in sample set or chromatogram)
	(b) (4)	Assay (5/30/2024)	Three blanks injected from blank solutions at the (b) (4) of sequence (i.e., (b) (4) three injections, different vials, one injection each vial), and (b) (4) standards after (b) (4) (b) (4) sample injections (b) (4) of the sequence.	Three blank injections at the (b) (4) of the sequence, ***two injections from same vial "blank 4"*** and one injection from (b) (4) standard at the (b) (4) of the sequence
	(b) (4)	Related Substances (6/04/2024)	Three blanks injected from blank solutions at the (b) (4) of sequence (i.e., (b) (4) three injections, different vials, one injection each vial), and (b) (4)	Three blank injections at the (b) (4) of the sequence, one blank injection following system

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Brandy N. Lepage
Digitally signed by Brandy N. Lepage -S
Date: 2024.11.18 19:15:39 -05'00'
Anthony Donato - S
Digitally signed by Anthony Donato -S
Date: 2024.11.18 19:07:55 -05'00'

DATE ISSUED
11/18/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Boulevard, 3rd Floor Parsippany, NJ 07054 (973) 331-4900	11/5/2024-11/8/2024; 11/12-11/15/2024; 11/18/2024
	FEI NUMBER 3033132864

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Michael Curry, Vice President of Operations	
FIRM NAME Empower Clinic Services New Jersey, LLC	STREET ADDRESS 203 Windsor Center Drive, Suite A16
CITY, STATE, ZIP CODE, COUNTRY East Windsor, NJ 08520-1410	TYPE ESTABLISHMENT INSPECTED Contract Testing Laboratory and Human Drug Compounding Outsourcing Facility

			standards after (b) (4) (b) (4) sample injections (b) (4) of the sequence.	suitability, two blank injections (separate vials), six sample injections, two blank injections (same vial), (b) (4) standard injection

OBSERVATION 7

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

Specifically, the critical alarms generated through operational and online quality monitoring parameters (i.e., (b) (4)) of the (b) (4) system (Equipment ID # MF-(b) (4)-018) installed in room #(b) (4) are not reviewed by the quality unit. During the walkthrough of the (b) (4) systems, (b) (6) QA Manager, indicated that the Quality Unit does not review the critical alarms, which are captured and stored, in the SCADA software DirectSOFT PLC, ver V6.1, generated by the (b) (4) system on a periodic basis.