DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	2/12/2020-3/6/2020* FEI NUMBER 3011887629

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arta Shaun Noorian, Founder & CEO

FIRM NAME	STREET ADDRESS
Empower Clinic Services, LLC	5980 W Sam Houston Pkwy N Ste 300
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77041-5251	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 I OBSERVED:

Building and Facilities

OBSERVATION 1

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

Specifically, your firm's procedure, T06.04 (b) (4) Environmental Monitoring System, Revision 02, requires that operators document differential pressure, relative humidity, and temperature monitoring before and during sterile drug production. Your procedure fails to require the recording and/or documentation of these results as part of your firm batch record. The Sterile Temperature, Pressure, and Humidity Monitoring Logs dated 2/4/2019 through 2/28/2020 demonstrated that your firm did not always document the differential pressure, relative humidity, and temperature before and during drug production in each ISO classified area. You failed to maintain adequate environmental controls during sterile drug production.

Production and Process Control

OBSERVATION 2

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

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	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 03-06-2020 10:36:30	3/6/2020

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Specifically, your firm failed to establish validated hold-times for sterilized bulk drug products to mitigate the risk of contamination of finished drug products. For example, the table below shows the date production process steps were performed for selected batch records.

Drug Product Description	Lot #	Formulation Date	(b) (4)	Fill Date (s)
Levprolide 10mg/ml	64738	(b) (4)		2/15/20
Glycine 50mg/ml	64619			2/14/20
Testosterone Cyp.in GSO (5 ml) 200 mg/ml Injectable	64579			2/14/20 & 2/15/20
Testosterone Cyp.in GSO (5 ml) 50 mg/ml Injectable	56796			8/28/19
Pyridoxine HCL (Vit B6) (30 ml) 100 mg/ml Injectable	62303			1/7/20

Your firm's management reported the firm has not established a written hold-time procedure.

Quality

OBSERVATION 3

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

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Specifically, your firm failed to adequately write and fully follow the following procedures applicable to your firm's quality unit:

A. Your firm failed to adequately implement your firm's change control procedure, T01.05 Good Documentation Practices, Revision 03 for changes made to approved protocols. For example;
   1. During a review of your firm's performance qualification report, (b) (4) Vial Washer, Model (b) (4) (b) (4) Performance Qualification Report, Version V 3.0 dated 6/27/2019, I found your firm made changes to the protocol reporting section without initiating a change control and receiving approval to revise the original approved protocol, (b) (4) Vial Washer, Model (b) (4) Performance Qualification Protocol, Version V 3.0 dated 6/27/2019.
   2. During a review of your firm's performance qualification report, (b) (4) (b) (4) Performance Qualification Report, Asset # (b) (4), Revision V.3 dated November 2019, Approved 11/12/2019, I found your firm made changes to the protocol reporting section without initiating a change control and receiving approval to revise the original approved protocol, (b) (4) (b) (4) Performance Qualification Protocol, Asset # (b) (4), Revision V.3 dated November 2019, Approved 11/12/2019.

B. Your firm failed to adequately implement your firm's written, procedure T08.19 Investigation of Non-conformance and CAPA Issuance procedure, Revision 03. For example, during a review of your firm's performance qualification report, (b) (4) (b) (4) Performance Qualification Report, Asset # (b) (4), Revision V.3 dated November 2019, Approved 11/12/2019, I found as a result of investigations into documented deviations, your firm's quality unit made changes to the acceptance criteria documented within the original protocol without obtaining your firm's management approval prior to its implementation and ultimate approval of the performance qualification.

OBSERVATION 4

Your firm compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, a) you compound drug products that are identical or nearly

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identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

A. Human Chorionic Gonadotropin
B. Menotropins Injection
C. Leuprolide Acetate Injection
D. Pyridoxine HCL Injection

This is a repeat observation.

OBSERVATION 5

The containers of your outsourcing facility's drug products does not include information required by section 503B(a)(10)(B). Specifically, your containers do not include the following information:

a) Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088;

Examples of your container labels that do not contain this information:

3. Testosterone Cypionate 200 mg/ml Injection
4. Testosterone Cypionate 50mg/ml Injection
5. HCG 12000 IU
6. HCG 6000 IU
7. FSH 1500 IU

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8. Menotropins (HMG) 500 IU
9. Ascorbic Acid Preserved 500mg/ml
10. Leuprolide Acetate 40MCG/0.2ml
11. Pyridoxine HCL (Vit B6) 100mg/ml
12. BCAA 30ml 15/10/40 MG/ML Injection
13. Taurine 50 mg/ml Injection
14. Omnitrope 5.8mg Injection
15. Glutathione Preserved 200mg/ml Injection

OBSERVATION 6

Your outsourcing facility has not submitted adverse event reports in 2019 FDA in accordance with the content and format requirements established through guidance (AE Reporting Guidance) or regulation under section 310.305 of 21 CFR.

***DATES OF INSPECTION**

2/12/2020(Wed), 2/13/2020(Thu), 2/14/2020(Fri), 2/19/2020(Wed), 2/20/2020(Thu), 2/21/2020(Fri), 2/24/2020(Mon), 2/26/2020(Wed), 2/27/2020(Thu), 2/28/2020(Fri), 3/02/2020(Mon), 3/03/2020(Tue), 3/06/2020(Fri)

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