


DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 01/10/2018-01/24/2018 FEI NUMBER 3011887629	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Mr. Arta Shaun Noorian, Founder and CEO			
FIRM NAME Empower Pharmacy		STREET ADDRESS 5980 West Sam Houston Parkway North Suite 300	
CITY, STATE AND ZIP CODE Houston, TX 77041		TYPE OF 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) (WE) OBSERVED:			
Observation #1			
There is a failure to thoroughly investigate any unexplained discrepancy or failure of a batch, regardless of whether the batch has been distributed, or a failure to expand an investigation to assess other batches that may also be impacted.			
Specifically,			
A review of your firm's endotoxin failure, occurring on 10/25/2017 for Lot No. 36029; Tri-Amino (L-Arginine HCL/L-Citrulline/L-Ornithine) 100/100/100 mg/mL, revealed that the investigation was incomplete in that:			
1) Your firm failed to document a root-cause for the endotoxin failure. 2) Your firm did not implement any corrective actions or preventative measures to assure that future endotoxin failures will not occur when manufacturing this product. 3) Your firm did not evaluate whether other associated lots were impacted.			
Review of your firm's potency failure, occurring on 10/16/2017 for Lot No. 35979; HCG Lyophilized 3000 IU/ vial, revealed that the investigation was incomplete in that:			
1) Your firm failed to document a root-cause for the potency failure. 2) Your firm did not implement any corrective actions or preventative measures to assure that future potency failures will not occur when manufacturing this product. 3) Your firm did not evaluate whether other associated lots were impacted.			
THIS IS A REPEAT OBSERVATION			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (<i>Print or Type</i>) Jason R. Caballero, CSO Sha'tina Alridge, CSO	DATE ISSUED 01/24/2018