DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Kansas City District Office/Division of Pharmaceutical Quality Operations III 8050 Marshall Drive, Suite 205 Lenexa, KS 66214 Phone: (913) 495-5100 Industry Information: www.fda.gov/oc/industry	07/10/2017 -07/27/2017
	FEI NUMBER 3003718003

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Seth A. Vanek, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Essential Pharmacy Compounding LLC	620 N. 114th St.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Omaha, NE 68154-1571	Producer of Sterile and Non-Sterile Drugs

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

Equipment, materials, and/or supplies are not cleaned prior to initiating aseptic production after the performance of smoke studies.

Specifically, the base for the smoke used in the study is (b) (4). There is no documented cleaning after the smoke study to remove residues from (b) (4). There is no verification check to ensure the removal of (b) (4) from the ISO 5 laminar flow hood after the completion of the smoke study.

Observation 2

Personnel engaged in aseptic processing failed to prevent cross-contamination on the working surface of the ISO 5 laminar flow hood work bench.

Specifically, a Technician was observed in the aseptic production room using a sterile wipe to clean her gloved hands between compounding different products; also, she used the same wipe to clean the ISO 5 hood work bench. This practice could lead to possible product contamination.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Kellia N. Hicks -S Digitally signed by Kellia N Hicks -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2300425960, cn=Kellia N Hicks -S Date: 2017.07.27 10:10:07 -05'00'	Kellia N Hicks, Investigator	07/27/2017

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Observation 3

Non-sterile disinfecting agents are used in the aseptic processing (ISO 5) area.

Specifically, For example, Disinfectants, (b) (4) are diluted with (b) (4) and then used in the ISO 5 processing area.

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	Kellia N Hicks	Kellia N Hicks, Investigator	07/27/2017