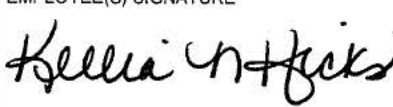


DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT OFFICE ADDRESS AND PHONE NUMBER Kansas City District Office/Division of Pharmaceutical Quality Operations III 8050 Marshall Drive, Suite 205 Lenexa, KS 66214 Phone: (913) 495-5100 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 07/10/2017 -07/27/2017  FEI NUMBER 3003718003	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED <b>TO: Seth A. Vanek, Pharmacist in Charge</b>			
FIRM NAME Essential Pharmacy Compounding LLC		STREET ADDRESS 620 N. 114th St.	
CITY, STATE AND ZIP CODE Omaha, NE 68154-1571		TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs	
<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>DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:</p> <p><b>Observation 1</b></p> <p>Equipment, materials, and/or supplies are not cleaned prior to initiating aseptic production after the performance of smoke studies.</p> <p>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.</p> <p><b>Observation 2</b></p> <p>Personnel engaged in aseptic processing failed to prevent cross-contamination on the working surface of the ISO 5 laminar flow hood work bench.</p> <p>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.</p>			
<span style="border: 1px solid black; padding: 2px;">Add Continuation Page</span>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  Kellia N. Hicks -S <small>Digitally signed by Kellia N. Hicks DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, ou=2142182920901001, +220942999, cn=Kellia N. Hicks Date: 2017.07.27 10:10:27 -0500</small>	EMPLOYEE(S) NAME AND TITLE (Print or Type)  Kellia N Hicks, Investigator	DATE ISSUED  07/27/2017

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<p>Observation 3</p> <p>Non-sterile disinfecting agents are used in the aseptic processing (ISO 5) area.</p> <p>Specifically, For example, Disinfectants, (b) (4) are diluted with (b) (4) and then used in the ISO 5 processing area.</p>			
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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE ( <i>Print or Type</i> ) Kellia N Hicks, Investigator	DATE ISSUED 07/27/2017