DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 10 Baltimore, MD 21215 (410) 779-5455 Fax: (410) 779-5707 Industry Information: www.fda.gov/oc/industry	09/19-21, 24-25/2018
	FEI NUMBER 3004610520

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: William S McFarland, Owner

FIRM NAME	STREET ADDRESS
Loop Plaza Pharmacy Company DBA Loop Compounding Phar	72 6th Ave
CITY, STATE AND ZIP CODE Saint Albans, WV 25177-2769	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non Sterile Drug Products

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

OBSERVATION 1
The ISO 5 classified area is located within a non-classified room (segregated production area).

Specifically, there is no assurance the cleanroom surrounding the ISO 5 laminar air flow hood is operating within classified conditions. The last certification was completed on February 22 2018 and was due for re-certification in (b) (4) The firm has produced approximately (b) products on a (b) (4) in the cleanroom since September.

OBSERVATION 2
Non-sterilized or non-depyrogenated tools or temporary containers were used in sterile drug production

Specifically, there is no assurance that the (b) (4) used to store bulk solution can maintain sterility through the (b) (4) . The firm produced bulk solution vials of Bupivacaine HCl 40mg/ml lot 09202018@9, Hydromorphone 100mg/ml lot 08092018@54, Morphine 100mg/ml lot 08272018@66, Clonidine HCl 2000 mcg/ml lot 08212018@27, and Hydromorphone 100mg/ml lot 08092018@54. These products are stored (b) (4) and are used for patient specific prescriptions, during which the (b) (4) . The Bupivacaine HCl (lot 09202018@9) and Hydromorphone (lot 08092018@54) were used in the production of prescription compound Hydromorphone HCl: Bupivacaine HCl 280 mg: 410 mg (b) (4) with prescription number (b) (6)

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Melissa Roy	Melissa T Roy, CSO	09/25/2018

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OBSERVATION 3

ISO-5 classified areas were not certified under dynamic conditions. Specifically, unidirectional airflow was not verified under operational conditions.

Specifically, no dynamic smoke studies were performed during the last cleanroom certification on February 22, 2018 to demonstrate unidirectional airflow is maintained in the firm's (b) (4) ISO 5 hoods used to produce aseptically filled products. This is a repeat observation from the previous inspection.

OBSERVATION 4

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, media fills performed by the operators do not simulate the aseptic filling process under normal operating conditions. The operator can fill up to (b) (4) of a drug product in (b) (4), however the current media fill procedure only has the operator (b) (4)

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