

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax: (410) 779-5707	DATE(S) OF INSPECTION 12/12/2016-12/16/2016 FEI NUMBER 3004610520
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED William S. McFarland , Owner
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FIRM NAME Loop Pharmacy & Home Medical	STREET ADDRESS 72 6th Ave
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CITY, STATE, ZIP CODE, COUNTRY Saint Albans, WV 25177-2769	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products
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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:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the to produce aseptic conditions.

Specifically,

- 1) Cleaning of the ISO 7 and ISO 8 rooms and the ISO 5 laminar air flow benches used to produce aseptically filled drug products does not include a sporicidal agent.
- 2) Drug spills in the ISO 5 laminar air flow benches used to produce aseptically filled drug products are cleaned using (b) (4) poured into a previously used sterile (b) (4) spray bottle.
- 3) There is no data to show that the use of (b) (4) to perform smoke studies in the ISO 5 hoods used to produce aseptically filled products is adequately removed by the cleaning procedures used.
- 4) Four objects that appear to be dead bugs are located between the ceiling and the protective cover of the light fixture in front of the smaller ISO 5 bench in the ISO 7 room.

OBSERVATION 2

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

There is insufficient test data supporting the labeled Beyond Use Date (BUD) provided for some injectable products or (b) (4) For example:

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- 1) There is no assurance that (b) (4) sterilized and aseptically filled sterile drug products, including Glycerin 98.5 Ophthalmic with a labeled expiry period of one month (refrigerated), are stable over the labeled expiry period.
- 2) There is no potency, sterility, or endotoxin data to support that the container closure systems for the (b) (4) preservative-free morphine, hydrocodone, bupivacaine, and baclofen solutions (b) (4) (b) (4) aseptically filled intrathecal pain pump refills are not adversely affected by the storage in a freezer in an uncontrolled area, up to (b) (4) removals from the freezer in a week, 45 day BUD, (b) (4) of the (b) (4) vial, or the practice of (b) (4) the vials to (b) (4) and do not adversely affect the finished aseptically filled drug products that are stored refrigerated with BUDs of 14 days.
- 3) There is no data to support the 14 day refrigerated BUD of preservative-free aseptically filled intrathecal pain pump refills (b) (4) of morphine, hydrocodone, bupivacaine, and baclofen.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

- 4) Glycerin 98.5 Ophthalmic is sterilized in a (b) (4) , and then (b) (4) t.
- 5) During production of aseptically filled hydromorphone intrathecal pain pump refill syringes on 12/14/16, the pharmacist placed (b) (4) (b) (4) (b) (4) gloved hands between the ISO 5 airflow and the product several times, including while attaching needles to (b) (4) syringes, when attaching (b) (4) and while attaching the (b) (4) was (b) (4).

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- 6) Smoke studies to demonstrate that unidirectional airflow is maintained in the ISO 5 hood used to produce aseptically filled products do not include all of the operations affecting airflow in the hood, such as setting up (b) (4) compounding operations (b) (4)

OBSERVATION 4

Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform.

Specifically,

Gowns worn during the production of aseptically filled products in the ISO 5 hood are placed on and against non-sterile surfaces before being used in the ISO 5 area and are re-used multiple times throughout the day.

OBSERVATION 5

Drug product containers and closures were not sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically,

- 1) There is no data to support the effectiveness of the (b) (4) and (b) (4) (b) (4) used to sterilize in-process equipment, glassware, and finished product containers and closures used in the production of aseptically filled drug products and to sterilize (b) (4) sterilized Glycerin 98.5 Ophthalmic.
- 2) (b) (4) used to demonstrate the effectiveness of the (b) (4) used to sterilize and depyrogenate glassware used in the production of aseptically filled drug products and to sterilize (b) (4) sterilized Glycerin 98.5 Ophthalmic are incubated at (b) (4) instead of (b) (4) as specified in the manufacturer's instructions.

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- 3) The printouts showing the (b) (4) (b) (4) used to sterilize in-process equipment used in the production of aseptically filled drug products are kept as (b) (4) (b) (4) for (b) (4) with no handwritten records, notes, or other means to correlate specific (b) (4) to specific batches or pieces of equipment.

OBSERVATION 6

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Methylcobalamin 100 mcg/ml for injection lot 03172016 was tested for potency on 3/22/2016 and found to be sub-potent, with an assay of 71.1% of the label claim. There was no evidence that this failure was investigated or that any action was taken to correct the issue or prevent it from reoccurring.

OBSERVATION 7

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically,

There is no data to support the current practice of keeping depyrogenated glassware and final containers (b) (4) in the ISO 7 room for (b) (4).

OBSERVATION 8

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

Specifically,

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- 1) Non-viable particulate monitoring and active air sampling for viable particulates in the ISO 5 area is performed (b) (4) .
- 2) During production of aseptically filled hydromorphone intrathecal pain pump refill syringes on 12/14/16, the pharmacist sprayed (b) (4) near the open settling plates used to monitor microbial contamination, with (b) (4) mist entering the plates.
- 3) The pressure gauge between the ISO 7 and 8 rooms read 0.005" WC before, during, and after aseptic processing activities on 12/12/16 and 12/14/16 when read at eye-level despite the fact that the SOPs for aseptic processing state that the minimum pressure differential between these rooms is (b) (4)

OBSERVATION 9

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

Aseptically filled and (b) (4) sterilized sterile drug products, including Glycerin 98.5 Ophthalmic, are not tested for sterility or endotoxin.

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