DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772	9/12/2016-9/16/2016
	FEI NUMBER 1530045

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sherrie L. Cohen-Merchant , Owner

FIRM NAME	STREET ADDRESS
Crosbys Drugs Inc	2609 N High St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Columbus, OH 43202-2555	Producer of Sterile Drugs

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

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

Specifically,

1) (b)(4) papaverine in (b)(4) during the production of Tri-Mix on 9/13/16, the employee producing the batch touched the uncovered (b)(4) with their bare hands.
2) There are no smoke studies to demonstrate the effectiveness of the ISO 5 hood used to produce aseptically filled products.
3) No data is available for the process simulation tests (media fills) performed to date.

OBSERVATION 2

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

Specifically,

Gowns and face coverings worn during the production of aseptically filled products in the ISO 5 hood are not sterile and are re-used multiple times throughout the day.

OBSERVATION 3

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Matthew B Casale, Investigator Invalid signature X Matthew B Casale Matthew B Casale Investigator Signed by: Matthew B. Casale -S	9/16/2016

Specifically,

Equipment in direct contact with aseptically filled products, such as (b)(4) and (b)(4) used to (b)(4) papaverine used to produce Tri-Mix, are cleaned with (b)(4) and sterile (b)(4) and not depyrogenated before use.

OBSERVATION 4

The flow of components and in-process materials though the building is not designed to prevent contamination.

Specifically,

Equipment is not disinfected when moved from the ISO 7 clean room into the ISO 5 hood used for producing aseptically filled products.

OBSERVATION 5

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

Specifically,

1) Non-viable particulate monitoring and active air sampling for viable particulates in the (b)(4) is performed (b)(4).
2) Surface sampling of the (b)(4) is performed (b)(4).
3) Fingertip plating for personnel (b)(4) is performed (b)(4).
4) No data is available for the environmental and personnel monitoring performed to date, except for the room qualification performed in (b)(4).

OBSERVATION 6

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.

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Specifically,

There is no data to support that the container closure system for the (b)(4) alprostadil (b)(4) (b)(4) used to produce aseptically filled Tri-Mix is not adversely affected by the storage conditions, (b)(4), and (b)(4) of the (b)(4)

OBSERVATION 7

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 sterile drug products, including Tri-Mix, Gentamycin Bladder Irrigation Solution, Quad-Mix, and Acetylcysteine Eye Drops, are not tested for sterility or endotoxin.

OBSERVATION 8

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

Specifically,

There is no assurance that the finished aseptically filled Tri-Mix, which is produced by (b)(4) (b)(4), is stable over the labeled expiry period of 45 days (frozen).

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