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.
Specifically,

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

**OBSERVATION 4**

The flow of components and in-process materials through 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 is performed.

2) Surface sampling of the is performed.

3) Fingertip plating for personnel is performed.

4) No data is available for the environmental and personnel monitoring performed to date, except for the room qualification performed in.

**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.
Specifically, there is no data to support that the container closure system for the alprostadil used to produce aseptically filled Tri-Mix is not adversely affected by the storage conditions of the As of the

**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 As of the

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SEE REVERSE OF THIS PAGE

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DATE ISSUED 9/16/2016