

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

DISTRICT ADDRESS AND PHONE NUMBER 8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax: (913) 495-5115	DATE(S) OF INSPECTION 8/29/2016-9/21/2016*
	FEI NUMBER 3012104093

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gregory A. Rockers, RPh. , President

FIRM NAME Fagron Compounding Services LLC dba Fagron Sterile Services	STREET ADDRESS 8710 E 34th St N
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CITY, STATE, ZIP CODE, COUNTRY Wichita, KS 67226-2636	TYPE ESTABLISHMENT INSPECTED 503B Outsourcing Facility
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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

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

A) Visual inspection of finished drug product is performed by inspectors without adequate training and qualification. Visual inspection training does not include showing inspectors examples of the types of defects they are looking for. Additionally, the firm does not have defect library of possible defects. Furthermore, inspectors have not been tested to establish their ability to locate defects and categorize them as required in their visual inspection form.

B) Visual inspection is not performed as required by the firm's written procedure. I observed the visual inspection Mitomycin lot 160829@001F (BUD 11/5/16) by ^{(b) (6), (b) (7)(C)}. Per the firm's written procedure Visual Inspection and Defect Recognition (9.200.FSS), the operators must ^{(b) (4)}, however I observed this was not done on any of the syringes in the lot. During the inspection, I visually examined retain samples for Mitomycin lot 160328@001F (BUD 6/5/16) and saw apparent particulate, clumping, and/or cloudiness in all retains.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Brett R Havranek, Investigator	DATE ISSUED 9/21/2016
		<input checked="" type="checkbox"/> Brett R. Havranek Investigator Signed by: Brett R. Havranek-S

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Specifically,

A) The firm's (b) (4), which (b) (4) such as (b) (4) has had approximately 766 critical alarms in areas used for production since March 8, 2016. The firm has not documented deviations and performed investigations on any of these alarms they have deemed critical. Alarm records are not reviewed concurrently with batch records at product release. The firm does not have a written procedure describing the alarms, their classifications, and when investigations are required.

B) Mitomycin lot 160406@001F was released without conducting (b) (4) to ensure (b) (4) was lost and never tested, and the firm did not recognize this and investigate appropriately prior to release of the lot. An investigation conducted after lot release did not establish how/where the (b) (4) was lost.

OBSERVATION 3

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

Specifically,

During the aseptic production of Mitomycin Bladder Irrigation Solution 20mg/40mL in 60 mL Syringes lot 160829@001F on 8/29/16, I observed:

- a) Personnel performing the aseptic compounding and filling of sterile drug product wear masks which are not sterile and which the outer surface has not been shown to be non-linting/non-shedding. These masks have small fibers too numerous to count protruding from their outer surface.
- b) The non-sterile masks and sterile cloth hoods worn by operators have an air gap between them, and the operator's skin can be seen between the mask and hood at some times during production.

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OBSERVATION 4

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

Specifically,

Media fill records do not document a significant worst-case step occurring. During syringe filling of Mitomycin lot 160829@001F, I observed the operator fill syringes, then (b) (4)

This step is the only time the product is outside a closed system and exposed to air from the filling environment, but it is not documented as having occurred during the media fills and is also not documented in product batch records.

***DATES OF INSPECTION**

8/29/2016(Mon),8/30/2016(Tue),8/31/2016(Wed),9/01/2016(Thu),9/02/2016(Fri),9/12/2016(Mon),9/13/2016(Tue),9/21/2016(Wed)

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