DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	6/10/2019-6/21/2019* FEI NUMBER 3012104093

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Carl D. Woetzel, President

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

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

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,
A) On 6/12/19 during a walkthrough of your firm's aseptic processing areas, I observed in (b) (4) laminar flow hood (Equipment ID#FSS-1050) cleanroom suite (b) (4) a brown/black residue on the inside of the LFH bottom left (b) (4) panel between the panel and the metal bench table lip edge. (Photograph taken) Aseptic processing of Glycopyrrolate 0.2mg/ml injection 5 ml syringes, batch#(b) (4) was being aseptically filled at this time.

B) On 6/12/19 during a walkthrough of your firm's aseptic processing areas, I observed in (b) (4) laminar flow hood (Equipment ID# FSS-1053) cleanroom suite (b) (4) cracked (b) (4) side panels from the overtightening of two connecting screws. In the cracking area around the screws a brown residue was observed. (Photograph taken) Aseptic processing of Succinylcholine chloride injection 20mg/ml batch# (b) (4) was being aseptically filled at the time.

OBSERVATION 2

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,
There is no testing of the preservative content in the injectable drug products at time of release or during beyond use dating studies. The following injectable solutions contain preservatives:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Erika V Butler, Investigator	X Erika V Butler Investigator Signed By: Erika V. Butler -S Date Signed: 06-21-2019 11:04:01	6/21/2019

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- Succinylcholine Chloride 20mg/ml injection contains methylparaben as a preservative
- Neostigmine Methylsulfate 1mg/ml injection contains phenol as a preservative
- Glycopyrrolate 0.2 mg/ml injection contains benzyl alcohol as a preservative
- Sodium citrate 4% solution contains (b) (4) as a preservative
- Sodium citrate 4%/Gentamicin 320 mcg/ml contains (b) (4) as a preservative
- Ketamine 50 mg/ml contains benzethonium chloride as a preservative

OBSERVATION 3

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

On 6/12/19 and again on 6/13/19, I observed aseptic operators in the clean room suites (b) (4) and (b) (4) respectively; wearing a goggle type in the ISO 5 (b) (4) laminar flow hood which contained numerous holes (approximately 50) for direct venting. Aseptic operators were at the time performing aseptic filling for sodium thiosulfate in 50 ml vials (Suite (b) (4) and a development batch for morphine 3ml syringes.

OBSERVATION 4

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

Specifically,

The monitoring for non-viable particulates is not located in close proximity to the aseptic operator located on the (b) (4) side of the laminar flow hood performing aseptic manipulations. The particle counter is located on the (b) (4) of the (b) (4) laminar flow hood. Two operators work simultaneously on the right and left side of the bench. The non-viable particle counter position is not in close proximity of the aseptic manipulations for the aseptic technician on the (b) (4) side of the laminar flow hood.

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OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

Media Fill study FSS 2018-030 (11/2018) for the 10 ml syringe, 5 ml fill does not contain information results of the incubated (b) (4) units and the conclusionary results of the media fill. There is no final report describing study results, if positive units were found and if the media fill met the protocol acceptance criteria.

OBSERVATION 6

There is a failure to thoroughly review any unexplained discrepancy and 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,
Investigations are not complete and do not always include a full investigation. Out of specification investigations do not include a review of the manufacturing process as required by your SOP 1.040.FSS, revision 2.0.
For example, the following OOS investigations were incomplete:

a) Neostigmine methylsulfate lot# C74-00010275 compounded on 4/30/19, Beyond Use Date 9/27/2019 received an OOS for assay with a result of 115.6% (limits (b) (4)%). No assignable root cause in the initial lab investigation. The original sample vial was (b) (4) and a revial of the original sample prep were performed; results were 115.2% and 115.5%, respectively. This confirms the original OOS. A triplicate retest was performed along with a 4th confirmatory test. All within specifications:(b) (4) (b) (4) %. A (b) (4) test was applied and considered the original result an outlier. The original result was invalidated. There was no full investigation or review of the compounding formulation records and process. Batch was released.

b) Rocuronium Bromide 10 mg/ml lot# C274-000009195 compounded on 2/22/19, Beyond Use Date 8/21/2019 received an OOS for assay with a result of 84.5% (limits (b) (4)%). No assignable root cause

in the initial lab investigation. The original sample vial was (b) (4) and a revial of the original sample prep were performed; results were 90.5% and 108.1%, respectively. A triplicate retest was performed along with a 4th confirmatory test. All within specifications: (b) (4) %. The root cause was an unknown sample error. There was no full investigation or review of the compounding formulation records and process. Batch was released.

c) Glycopyrrolate 0.2mg/ml lot#C274-000006719 compounded on 9/5/18, Beyond Use Date 2/2/2019 received an OOS for assay with a result of 86.2% (limits (b) (4)%). No assignable root cause in the initial lab investigation. The original sample vial was (b) (4) and a revial of the original sample prep were performed; results were 86.3% and 86.9%, respectively. Two retests and three resamples were performed. All within specifications: (b) (4) The root cause was an unknown sample error. There was no full investigation or review of the compounding formulation records and process. Batch was released.

d) Sodium Thiosulfate 25% lot# C274-000010672 compounded on 5/23/19, Beyond Use Date 8/21/2019 received an OOS for endotoxins with a result of 4.0301 EU/ml limits are (b) (4) EU/ml. Preliminary investigation could not assign a cause to the OOS. Retesting was performed in triplicate by (b) (4) analyst. The results were within specifications. The root cause was "sample prep error or it is likely the product sample well was contaminated". There was no full investigation or review of the compounding formulation records and process. Batch was released.

e) Customer complaint 0119-01 initiated on January 2, 2019 reported one of the Succinylcholine Chloride syringes lot C274-000007865 did not have a label. There is no documentation of the investigation to the complaint.

OBSERVATION 7

Packaged and labeled products are not examined during finishing operations to provide assurance that containers and packages in the lot have the correct label.

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Specifically,

Your firm does not collect a representative number of finished drug products for an evaluation and documentation of correct labeling.

OBSERVATION 8
Adverse drug event information has not been reported to FDA.

Specifically,
Your firm has received 16 complaints of serious unexpected events concerning lack of pharmacological effect which has not been reported to the FDA.
Year 2019:

Complaint #	Description	Product name	Lot
0319-023,0319-032	Lack of effect	Rocuronium bromide injection 10mg/ml	C274-000008848, C274-000008698
0519-010	Lack of effect	Rocuronium bromide injection 10mg/ml	C274-000009444
0519-011	Lack of effect	Rocuronium bromide injection 10mg/ml	C274-000008690
0519-012	Lack of effect	Rocuronium bromide injection 10mg/ml	C274-000008796
0519-018	Lack of effect	Succinylcholine Chloride 20mg/ml	C274-000009398
0519-019	Lack of effect	Rocuronium bromide injection 10mg/ml	C274-000009443
0519-024	Lack of effect	Rocuronium bromide injection 10mg/ml	C274-000009597
0519-025	Lack of effect	Rocuronium bromide injection 10mg/ml	C274-000009588
0519-033	Lack of effect	Rocuronium bromide	C274-

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		injection 10mg/ml	000009325
0619-002	Lack of effect	Phenylephrine HCL 100mcg/ml	C274-000009992

Year 2018:

Complaint #	Description	Product name	Lot
1118-006	Lack of effect	Succinylcholine Chloride 20mg/ml	C274-000006623
1118-002	Lack of effect	Phenylephrine HCL 100mcg/ml	C274-000006801
1118-012	Lack of effect	Succinylcholine Chloride 20mg/ml	C274-000007436
1218-003	Lack of effect	Succinylcholine Chloride 20mg/ml	C274-000006774

Year 2017:

Complaint #	Description	Product name	Lot
0417-001	Lack of effect	Rocuronium bromide injection 10mg/ml	161117@002F
1217-007	Lack of effect	Rocuronium bromide injection 10mg/ml	C274-000002186

OBSERVATION 9

Your firm compounded drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, you compound drug products that are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing;
Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

Drug name	Package	Dosage	Route of

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	description	form	Administration
Glycopyrrolate 0.2 mg/ml	5ml in syringe	Injection	Intravenous
Phenylephrine HCL 10mg/ml	10ml in syringe	Injection	Intravenous
Neostigmine Methylsulfate 1mg/ml	5ml in syringe	Injection	Intravenous
Succinylcholine Chloride 20mg/ml	10ml in syringe	Injection	Intravenous

OBSERVATION 10

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, your product labels do not include a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient. If there is no space on the product label, such information should be included on the container per section 503B(a)(10)(B)(i).

Examples of your drug product labels that do not contain this information:

- Sodium thiosulfate 25% injection
- Lidocaine hydrochloride 2% injection
- Lidocaine hydrochloride 1% injection
- Ketamine hydrochloride 50 mg/mL injection
- Succinylcholine chloride 20 mg/mL injection
- Neostigmine methylsulfate 1 mg/mL injection
- Glycopyrrolate 0.2 mg/mL injection
- Rocuronium bromide 10 mg/mL injection

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- Sodium citrate 4% injection containing gentamicin 320 mcg/mL
- Sodium citrate 4% injection
- Ketamine hydrochloride 50 mg/mL injection

2. The containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B). Specifically, your containers do not include the route of administration.

Examples of your container labels that do not contain this information:

- Sodium thiosulfate 25% injection
- Sodium citrate 4% injection containing gentamicin 320 mcg/mL
- Sodium citrate 4% injection

OBSERVATION 11

Bulk drug substances used by your outsourcing facility to compound drug products are not each manufactured by an establishment that is registered under section 510 as required by section 503B(a)(2)(C).

Specifically, the Trisodium citrate dihydrate API used in the manufacture of Sodium citrate 4% solution injection and Sodium citrate 4%/Gentamicin 320 mcg/ml solution injection is not manufactured in a FDA registered facility.

***DATES OF INSPECTION**

6/10/2019(Mon), 6/11/2019(Tue), 6/12/2019(Wed), 6/13/2019(Thu), 6/14/2019(Fri), 6/17/2019(Mon), 6/18/2019(Tue), 6/19/2019(Wed), 6/20/2019(Thu), 6/21/2019(Fri)

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