DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	7/30/2018-8/10/2018* FEI NUMBER 3006572203

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andrew J. Roseboom , Co-Owner and Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
Dolan Central Illinois Compounding LLC dba Preckshot Professional Pharmacy	5832 N Knoxville Ave, Ste E
CITY, STATE, ZIP CODE, COUNTRY Peoria, IL 61614-4300	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

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

Your facility was designed and/or operated in a way that permits poor flow of materials.

Specifically,

Materials are brought into the ISO 7 Buffer room directly from an unclassified area through (b) (4) (b) (4) For example, your firm utilizes this material (b) (4) to transfer in sterile processing supplies such as (b) (4) syringes, sterile (b) (4)(b) (4) spray bottles, sterile wipes, (b) (4) pharmaceutical grade (b) (4) and zip-lock bags.

I observed sterile production of Papaverine, Phentolamine, Alprostadil (15: 0.5: 25) in ML injectable, lot 07302018@18 for (b) (6) and Papaverine, Phentolamine, Alprostadil (25: 0.8: 20) in ML injectable, lot 07302018@17 for (b) (6) in your ISO 5 hood on 07/30/18.

OBSERVATION 2

Non-sterile bulk solutions are held for an extended period with no documentation to support the hold time.

Specifically,

Your firm prepares bulk stock solutions inside an uncertified hood and stores it inside a (b) (4) as an intermediary stock solution at (b) (4) to (b) (4) for up to (b) (4) days after processing without (b) (4) . For example, your firm produced (b) (4) of Alprostadil stock solution, lot 07122018@9 (Beyond use date 08/26/18) on 07/12/18. According to your firm management on 08/09/18, you do not require your intermediary stock solution

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to be (b) (4) prior to being (b) (4) for later use. Your firm utilized this lot of stock solution to produce the sterile products through (b) (4) in the ISO 5 hood on 07/12/18, 07/13/18, 07/16/18, 07/18/18, and 07/19/18.

Sterile product lots filled with Alprostadil stock solution lot 07122018@9

RX	LOT	DRUG	FILLED	BUD
(b) (6)	07122018@12	Phentolamine, Alprostadil Injectable 0.83MG/16.66MG	07/12/18	08/09/18
	07132018@11	Papaverine, Phentolamine, Alprostadil Injectable	07/13/18	08/10/18
	07132018@9	Papaverine, Phentolamine, Alprostadil Injectable	07/13/18	08/10/18
	07132018@6	Alprostadil 20MCG/ML Aqueous SOLN	07/13/18	08/26/18
	07162018@9	Phentolamine, Alprostadil Injectable 0.83MG/16.66MG	07/16/18	08/13/18
	~~17162018@8~~ **07162018@8**	Papaverine, Phentolamine, Alprostadil Injectable	07/16/18	08/13/18
	07162018@7	Papaverine, Phentolamine, Alprostadil Injectable	07/16/18	08/13/18
	07182018@9	Papaverine, Phentolamine, Alprostadil Injectable	07/18/18	08/15/18
	07182018@15	Papaverine, Phentolamine, Alprostadil Injectable	07/18/18	08/15/18
	07192018@7	Papaverine, Phentolamine, Alprostadil Injectable	07/19/18	08/16/18

OBSERVATION 3

Your firm prepares multi-dose sterile drug products with an extended beyond use date without preservatives.

Specifically,

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- Acetylcysteine Ophthalmic solutions are produced by your firm without preservatives. This ophthalmic solution is dispensed to your patients as a multi-dose sterile product with a beyond use date of 45 days in frozen/refrigerated conditions.

- Tacrolimus in Corn Oil NF Ophthalmic solutions are produced by your firm without preservatives. This ophthalmic solution is dispensed to your patients as a multi-dose sterile product with a beyond use date of 28 days in room temperature.

OBSERVATION 4

Disinfecting agents and cleaning pads used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

During sterile processing on 07/30/18, your Pharmacy Technician utilized non-sterile, low-shedding (b) (4) wipes sprayed with sterile (b) (4)(b) (4) to transfer sterile processing materials such as vials, syringes, and sterile (b) (4) (b) (4) spray bottles into the ISO 5 hood. I observed sterile production of Papaverine, Phentolamine, Alprostadil (15: 0.5: 25) in ML injectable, lot 07302018@18 for (b) (6) and Papaverine, Phentolamine, Alprostadil (25: 0.8: 20) in ML injectable, lot 07302018@17 for (b) (6) in your ISO 5 hood on 07/30/18.

OBSERVATION 5

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Equipment was not disinfected prior to entering the aseptic processing areas.

Specifically,

Prior to sterile processing, your firm attached a pre-moistened sterile (b) (4) to a (b) (4) mop head to sanitize the ISO 5 hood. I observed the foam mop head to be discolored with black colored residues on 07/30/18. I observed sterile production of Papaverine, Phentolamine, Alprostadil (15: 0.5: 25) in ML injectable, lot 07302018@18 for (b) (6) and Papaverine, Phentolamine, Alprostadil (25: 0.8: 20) in ML injectable, lot 07302018@17 for (b) (6) in your ISO 5 hood on 07/30/18.

***DATES OF INSPECTION**

7/30/2018(Mon), 7/31/2018(Tue), 8/01/2018(Wed), 8/02/2018(Thu), 8/03/2018(Fri), 8/07/2018(Tue), 8/09/2018(Thu), 8/10/2018(Fri)

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