

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

DISTRICT ADDRESS AND PHONE NUMBER

10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
(973) 331-4900 Fax: (973) 331-4969

DATE(S) OF INSPECTION

3/3/2016-4/15/2016*

FEI NUMBER

3012223534

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Svetislav Milic, R.Ph. , Owner

FIRM NAME

Colonia Care Pharmacy

STREET ADDRESS

515 Inman Ave Ste A

CITY, STATE, ZIP CODE, COUNTRY

Colonia, NJ 07067-1114

TYPE ESTABLISHMENT INSPECTED

Producer of 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

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

Specifically, there is insufficient test data supporting the labeled Beyond Use Date (BUD) provided for some injectable products or in-process sterile-filtered stock solutions used to prepare them. For example:

- Papaverine/Phentolamine/Prostaglandin-E1 Injection Solution ("Trimix"), lot 020216A, was prepared and filled on 2/2/16 in a multi-use vial, with a BUD of 30 days refrigerated, and 6 months when frozen. The finished product was not tested for sterility, and was made using in-house stock solutions prepared from non-sterile starting materials, one of which was expired (Papaverine stock solution expired approx. 23 days earlier, on 1/10/2016).

Each stock injection solution was prepared in a multi-use vial, and assigned a BUD of 1 to 6 months after filter sterilization, and stored in an unclassified area (Papaverine stock solution produced on 12/11/15, BUD 01/10/16; Phentolamine stock solution produced on 12/03/15, BUD 05/31/16; and Alprostadil stock solution produced on 12/11/15, BUD 06/08/16).

No data was provided demonstrating these stock solutions or finished sterile drug product have been evaluated for potency, purity, sterility, or endotoxin levels at the end of their labeled BUDs. The stock solutions may contain preservatives, but their effectiveness over the labeled BUDs in multi-use vials has also not been assessed.

- Methylcobalamin and Acetylcysteine Injection Solution, lot 120715M, was prepared and filled on 12/07/15 in pre-filled syringes, with a BUD of 30 days refrigerated, and 6 months when

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EMPLOYEE(S) SIGNATURE

Nicholas A Violand, Investigator

4/15/2016

DATE ISSUED

4/15/2016

Nicholas A Violand
Investigator
Signed by: Nicholas A. Violand, J.

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frozen. The finished product was not tested for sterility, and was made from an in-house stock solution, with BUD 04/05/16 (prepared 10/08/15), which is stored in an unclassified area. No data was provided demonstrating the stock solution or finished sterile drug product have been evaluated for potency, purity, sterility, or endotoxin levels at the end of their labeled BUDs, or that the container-closure system (syringes) used for the finished drug product is suitable for its intended use.

- Dexamethasone 24mg/ml Injectable, lot 031716N, was aseptically filled on 3/17/2016, with instructions to provide a BUD of "45 days after compounding date" but was labeled "06/01/16 Frozen", instead of the specified "5/1/2016" in the record. There was no sterility, potency, purity, or endotoxin testing performed to support the labeled BUD.

OBSERVATION 2

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

Specifically, not all finished sterile drug products are tested for sterility and endotoxin levels, where appropriate, and there is no testing schedule. For example:

- Papaverine/Phentolamine/Prostaglandin-EI Injection Solution ("Trimix"), lot 020216A, was prepared and filled on 2/2/16, and given a BUD of 30 days refrigerated, and 6 months when frozen. There was no testing of sterility or endotoxin levels of the finished drug product.
- Methylcobalamin and Acetylcysteine Injection Solution, lot 120715M, was prepared and filled on 12/07/15, and given a BUD of 30 days refrigerated, and 6 months when frozen. There was no testing of sterility or endotoxin levels of the finished drug product.
- Atropine Ophthalmic Solution, lot 020316J, was prepared and filled on 02/03/16, and given a BUD of 3 months. There was no testing of sterility of the finished drug product.

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Nicholas A Violand
Investigator
Signed by: Nicholas A. Violand-15

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- Hydrogen Peroxide Injectable, lot 010516G, was prepared and filled on 01/05/16, and given a BUD of 1 month. There was no testing of sterility or endotoxin levels of the finished drug product.

OBSERVATION 3

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

Specifically, in the laminar flow glovebox, which is located in an unclassified room and is used for aseptic filling of sterile drug products, the evaluation of unidirectional airflow continuity (e.g., smoke studies), airborne viable and non-viable particle counts, and surface monitoring for microbiological contamination are not performed under dynamic conditions that represent routine usage.

The air and surface monitoring are performed twice annually during recertification of the laminar flow glovebox when it is not being used, and not routinely during aseptic filling, which may occur daily or multiple times throughout the week. In addition, personnel monitoring consists of gloved fingertip monitoring (sterile gloves are donned over the gauntlet-gloves) every six months, and is performed as an independent operation, not after completion of aseptic filling, to represent routine conditions.

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically, twice-annual media fill testing is performed to support aseptic filling practices, in which 100ml of soybean casein digest media is prepared, sterile filtered, and filled into an unspecified number of "10 ml" vials, with a 5 ml control sample. This does not represent the most challenging conditions, in that up to 30 vials may be filled at one time. For example, Dexamethasone 24mg/ml Injectable, lot 031716N, was prepared on 3/17/16, and filled into 30 vials.

OBSERVATION 5

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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	<input checked="" type="checkbox"/> Nicholas A Violand <small>Nicholas A Violand Title: Investigator Signed by: Nicholas A. Violand</small>	

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Specifically, the filing record for Papaverine/Phentolamine/Prostaglandin-E1 Injection Solution, lot 020216A, executed 2/2/16, notes "Protect from light", but the finished drug product is prepared in "30ml Clear Sterile vial". There is no assurance the drug is adequately protected from light.

***DATES OF INSPECTION**
3/03/2016(Thu),3/07/2016(Mon),3/21/2016(Mon),4/04/2016(Mon),4/06/2016(Wed),4/08/2016(Fri),4/15/2016(Fri)

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		<input checked="" type="checkbox"/> Nicholas A Violand Investigator Signed by: Nicholas A. Violand JS