

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER One Montvale Avenue Stoneham, MA 02180 781-587-7500 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 02/22-24/2017; 02/28/2017; 03/01-03/2017
	FEI NUMBER 3012039582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Michael H. Roberge, Owner/Pharmacist In Charge

FIRM NAME Compounded Solutions in Pharmacy, LLC	STREET ADDRESS 810 Main Street
CITY, STATE AND ZIP CODE Monroe, CT 06468	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

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) (WE) OBSERVED:

OBSERVATION 1

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

Specifically, the pharmacist observed producing Triple P 10/0.5/16.6 Injectable Lot No. 02232017@8 on 02/23/2017 donned a disposable, non-sterile lab coat, rated for working in an ISO 7 environment, and sterile gloves with out sterile sleeves. The pharmacist was observed to extend ^{(b) (6)} forearms exposing the ISO 5 production environment and product to the non-sterile lab coat.

OBSERVATION 2

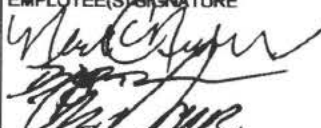
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically:

A. Your environmental monitoring program is deficient in that you do not perform monitoring of your classified spaces, including your ISO 5 working space and of personnel on a daily basis, rather it is performed ^{(b) (4)} and ^{(b) (4)}, respectively. This frequency is not sufficient to demonstrate conditions are consistently maintained.

B. Your firm does not continuously monitor the pressure differentials in your ISO8, ISO 7 and ISO 5 sterile production space in order to demonstrate that conditions are maintained throughout the operation. For example, continuous monitoring was not observed during the production of Triple P 10/0.5/16.6 Injectable Lot No. 02232017@8 on 02/23/2017.

ALL INFORMATION CONTAINED HEREIN IS UNCLASSIFIED

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Nealie C. Newberger, CSO Dien N. Nguyen, CSO Christopher (NMI) Janik, CSO	DATE ISSUED 03/03/2017
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OBSERVATION 3

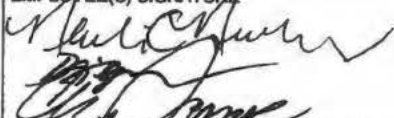
Aseptic processing areas are deficient in that ceilings are not smooth and/or hard surfaces that are not easily cleanable.

Specifically, on 02/23/2017 during the production of Triple P 10/0.5/16.6 Injectable Lot No. 02232017@8, unsealed ceiling tiles were noted in your ISO 7 clean room where your ISO 5 (b) (4) are located, and chipped/peeling caulking was noted on the ceiling tile in the adjacent ISO 8 ante-room where the (b) (4) of this Triple P lot: Papaverine HCL USP, Phentolamine (b) (4) Prostaglandin E1 (b) (4) occurred.

OBSERVATION 4

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

Specifically, before the production of Triple P 10/0.5/16.6 Injectable Lot No. 02232017@8 on 02/23/2017 it was noted that the pharmacist intended to use what appeared to be the same non-disposable, (b) (4) that he had used the previous day to (b) (4) Prostaglandin E1 (b) (4) for Triple P 30/1/10 Injectable Lot No. 0222017@13 without adequately washing it before use (e.g. with (b) (4)). The (b) (4) was only (b) (4) (b) (4). The pharmacist stated this was a typical practice. The pharmacist then procured a new (b) (4) and proceeded to produce Triple P 10/0.5/16.6 Injectable Lot No. 02232017@8 on 02/23/2017, and used the same non-disposal, (b) (4) to (b) (4): Papaverine HCL USP, Phentolamine (b) (4) Prostaglandin E1 (b) (4) with out washing in between, only (b) (4). The owner stated this was per the SOP, no data was provided to demonstrate this practice is adequate for cleaning the (b) (4).

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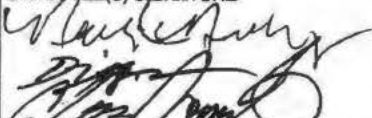
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OBSERVATION 5
 The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

Specifically, on 02/23/2017 the production of Progesterone SR 75mg capsules, Lot No. 02232017@10 was observed to take place on a lab bench in the general laboratory and not in a laminar flow hood (b) (4). At the same time on the same bench, Thyroid (60mg) 1 grain capsules, Lot No. 02222017@31 were being produced in the general laboratory and not in a LFH (b) (4). No other containment was provided.

***DATES OF INSPECTION**
 2/22/2017(Wed), 2/23/2017(Thr), 2/24/2017(Fri), 2/28/2017(Tue), 3/1/2017(Wed), 3/2/2017(Thr), 3/3/2017(Fri)

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