

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

DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax: (718) 662-5661 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 04/04/2016 - 04/20/2016*
	FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Joseph Navarra, President/ Owner

FIRM NAME Town Total Compounding Center	STREET ADDRESS 532 Broadhollow Road
CITY, STATE, ZIP CODE, COUNTRY Melville, NY 11747	TYPE ESTABLISHMENT INSPECTED Producer of Sterile & 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

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

Specifically, there is no written stability program to support assigned expiration dates for sterile compounded sterile preparations.

Additionally, when assigning expiry dates, you do not follow your written standard operating procedure titled "*Assignment of Beyond-Use Date for Sterile Compounded Preparations*". Examples include:

- i. Preservative-free products such as sterile ophthalmic solutions that do not have adequate stability data AND lack a sterility test have been assigned beyond use dates/ expiry periods that exceed the requirements of your written procedure. Specifically, the SOP states when assigning BUDs for "*compounded drug preparations*" that lack sterility testing, the date should be NMT 3 days under refrigeration and NMT 24 hours for ambient room temperature for "*high risk*" drug products. Examples include:
 - Glycerin 100% Lot Number 44462015 was assigned an expiry date of 5/14/2016, 180 days after compounding date of 11/6/2015. Additionally this lot of Glycerin was sterilized (b) (4), below the required sterilization (b) (4)
 - Glycerin 72% (w/v) Injectable Lot number 03252016@10 was assigned an expiry date of 6/23/2016, 90 days after compounding date of 3/25/16.

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- Rx (b) (6) Glycerin 72%/Lido1%-Epi 1:100000 was assigned an expiry date of 6/30/16, 90 days after compounding date of 4/1/16.
 - Pilocarpine HCl 2% Opth Soln was assigned an expiry date of 4/29/16, 28 days after compounding date of 4/1/16
 - Rx (b) (6) Ceftriaxone Nasal 2.5ml Nasal Soln was assigned an expiry date of 6/8/16, 90 days after compounding date of 3/10/16
 - Rx (b) (6) was assigned an expiry date of 6/30/16, 90 days after compounding date of 3/28/16
 - Rx (b) (6) was assigned an expiry date of 9/4/16, 180 days after compounding date of 3/8/16
- ii. Products *with* preservative that also lack stability and sterility date have been assigned beyond use dates (expiration dates) that exceed 48 hours at room temperature, or 14 days at refrigerated conditions as required by your procedure. Examples include:
- Mold Only Red Stage 4 indoor 5 was assigned a beyond use date of 12/1/17, 1095 days after compounding date of 3/10/16
 - Rx (b) (6) (Trimix #4) was filled on 3/28/16 and assigned an expiry date of 6/30/16, approximately 90 days later.

OBSERVATION 2

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically:

- a) Smoke studies were not performed for the (b)(4) ISO 5 laminar flow hoods (b) (4) under dynamic conditions to verify that operators, equipment or activities do not alter or impede the

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unidirectional flow of air from the HEPA filters in the ISO 7 room where products are aseptically processed. In addition, the ISO 5 laminar flow hood in the non-classified (b)(4) area lacks a smoke study under dynamic conditions.

b) The (b)(4) room pressure monitors used to monitor differential pressure of the ISO 7 clean room and ISO 8 ante room lack documentation of the pressure readings during days of production.

c) Specifically, there are no separate or defined areas for the compounding of sterile preparation to prevent contamination from hormone drug products and allergenic test preparations. These products contained in glass vials are processed in the same clean room and laminar flow hoods as other sterile drug products. Examples include:

- Mite Cockroach Epithelium Injection Rx (b)(6)
- Mold Only Injection Rx (b)(6)
- Oxytocin 24U/spray nasal spray - 20ml filled 3/29/16
- Hydroxyprogesterone caproate inj. 250mg/ml - 5ml filled 3/21/2016
- Testosterone propionate inj. 40mg/ml - 24ml filled 1/15/16

OBSERVATION 3

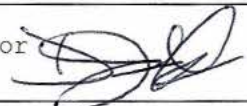
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, the (b)(4) sterilization processes used to sterilize compounded drug products made from non-sterile API (active pharmaceutical ingredients) lack assurance because of the following:

a) Sterilization (b)(4) have not been validated for products processed in the (b)(4) area. Examples of drug products include:

- Progesterone in oil 100mg/ml
- Hydroxyprogesterone caproate 250mg/ml inj
- Nandrolone 200mg/ml inj

b) Sterilization (b)(4) have not been validated for products processed in the (b)(4) area.

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Examples of drug products include:

- Castor oil 2% eye drops
- Prednisolone acetate PF eye drops 1%
- Carboxymethylcellulose PF eye drops 0.625% and 0.95%
- Glycerin 100%

- c) There is no documentation of the use of (b) (4) .
- d) There is no maintenance and calibration program for (b) (4) .
- e) Media fills/process simulations have been deficiently conducted. They have not been performed under the most stressful or challenging conditions/worst case scenario and according to a written protocol. In the absence of a media fill protocol to follow, you have not demonstrated that procedures and techniques that most closely resemble those used during routine aseptic filling of sterile drug products at your facility were used during the simulation. Without defining the frequency of interventions, type of intervention, the minimum duration time of filling operations simulated, the amount of employees inside the processing area for defined periods of time, there is a lack of demonstration that you have fulfilled the purpose of your media fill process. The rationale chosen for the conditions or activities simulated is neither written nor defined.

Additionally, testing is not performed per the (b) (4) manufacturer's instructions titled "(b) (4) ", in that:

- a. the vials are incubated for only (b) (4) , not (b) (4) as required
- b. The vials are not examined daily or every few days for turbidity. They are read only at (b) (4)
- c. There are no written procedures on how to conduct the visual exam, the frequency and acceptance criteria.

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OBSERVATION 4

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

- a) Environmental monitoring for viable air counts in the ISO 5, ISO 7 and ISO 8 areas is not performed at least once daily during periods of production.
- b) Current environmental sampling of surfaces and gloved personnel is not done according to the frequency required by your own written standard operating procedure, SOP titled "*Environmental Monitoring of the Clean Room Facility*". Specifically:
 - i. Surface sampling in the (b) (4) is conducted (b) (4) instead of (b) (4)
 - ii. Personnel monitoring which consists only of sampling the fingertips of gloved personnel is conducted (b) (4) instead of (b) (4) as required.
- c) There are no alert or action limits specified in your written procedure titled "*USP Proposed Levels for Air and Surface Monitoring*" based upon your written statement that "(b) (4) _____", even though you have been sampling since 2013.
- d) Environmental monitoring for non-viable particulates in the (b) (4) is not performed under dynamic conditions and is monitored (b) (4).
- e) Failing results obtained during environmental monitoring were not investigated for the following:
 - a) For surface sampling conducted in the (b) (4) on the following dates:

(b) (4)

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- b) For the (b) (4) facility personnel (b) (4) log, failures were noted on the following dates:
- 9/2/13
 - 9/30/13

OBSERVATION 5

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, given the observed inadequate environmental and process controls, current testing is inadequate in that:

There is a lack of justification for not testing each batch purporting to be sterile and/or pyrogen free. Currently you have not tested approximately (b) (4) % of all your sterile drug products.

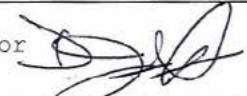
OBSERVATION 6

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

Specifically, sterile drug products are aseptically manipulated by cleanroom operators who were observed wearing non-sterile gowns, non-sterile footwear and non-sterile facial masks.

*** DATES OF INSPECTION:**

04/04/2016(Mon), 04/05/2016(Tue), 04/06/2016(Wed), 04/07/2016(Thu), 04/08/2016(Fri), 04/11/2016(Mon), 04/14/2016(Thu), 04/20/2016(Wed)

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