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 Industry Information: www.fda.gov/oc/industry	05/06/2015 - 07/09/2015* FEI NUMBER 3004504906

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Joel R. Frieders, Vice President

FIRM NAME	STREET ADDRESS
Techni Med, Inc. dba The Compounder	340 Marshall Ave Unit 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Aurora, IL 60506-5649	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

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

Specifically, the firm does not have adequate control systems in place to ensure sterile drug products are produced under aseptic conditions. The firm's environmental monitoring program does not adequately monitor environmental conditions that could impact aseptic processing operations. For example,

A. The firm does not perform viable or non-viable monitoring inside the ISO5 laminar flow hood or adjacent ISO 7 clean room while performing aseptic processing operations. The firm performs viable air monitoring in the ISO 5 zone (b) (b) contact surface sampling (b) (4) (b) (4) and non-viable monitoring is performed (b) (4).

B. The firm does not perform monitoring on personnel. The firm does not sample personnel gloves or other locations on personnel such as arm(s) or chest of gowns during routine aseptic processing operations or during media fill studies.

C. The firm has not validated its environmental monitoring microbiological test method to ensure that disinfectants used in cleaning will not interfere with recovery of microorganisms.

OBSERVATION 2

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

Specifically, the firm's personnel do not wear sterile gowning during the compounding of sterile drug products. On 05/06/2015, I observed a pharmacy technician wear a non-sterile gown while compounding an intrathecal drug product, Clonidine Batch PF 4mg/ml, lot 05062015:60@20 and on 05/07/2015, I observed a pharmacy technician wear a non-sterile gown while compounding an intrathecal drug product, Baclofen 1000mcg/ml Inj., Lot 05072015:88@15.

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	Christina A. Miller, Investigator	07/09/2015

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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,

A. The firm did not adequately validate that the firm's current aseptic processing conditions will not introduce the potential for microbial contamination. The firm's media fill studies did not adequately simulate the most complex processing conditions that could provide a challenge to aseptic operations.

B. The firm has not validated the (b) (4) sterilization (b) (4) that are used to sterilize drug products such as Progesterone (17 A-Hydroxy) Caproate (b) (4) 250mg/ml Inj and Estradiol Valerate in Cottonseed Oil 40mg/ml Inj.

C. Dynamic smoke studies have not been performed in the ISO 5 laminar flow hoods to ensure air patterns are suitable for aseptic conditions.

D. Equipment qualification studies have not performed on the (b) (4) used to sterilize drug products.

OBSERVATION 4

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

A. The firm does not have established procedures on the frequency of replacing the HEPA filters located in the ISO 5 laminar flow hoods. The firm has not changed out the HEPA filter in its ISO5 laminar flow hood (b) (4) since September 2005 and its ISO5 laminar flow hood (b) (4) since June 2009.

B. Temperature and pressure are not monitored continuously in the firm's cleanroom complex. The firm (b) (4) checks both temperature and pressure (b) (4).

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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,

A. None of the firm's sterile drug products produced in the three months prior to the start of this inspection have been tested for pyrogens. The firm produces sterile drug products that are administered intrathecal, intravenously, and intramuscular.

B. The firm has not validated that its (b) (4) microbiological test method used for in-house sterility testing can adequately detect and recover microorganisms. The firm states that they currently use a (b) (4) (b) (4) The firm also has not established a written procedure detailing the sterility test method. The firm uses this (b) (4) microbiological test method for sterility testing of product lots that are (b) (4) (b) (4) All of the firm's intrathecal drug products are produced in (b) (4) and use the (b) microbiological test method to determine sterility.

OBSERVATION 6

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

Specifically, the firm does not test its sterile drug products for potency as part of the sterile drug products' final approval and release.

OBSERVATION 7

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, the firm has not conducted hold time studies to support the "use by" dates assigned to (b) (4) that are stored at refrigerated temperatures. The firm currently assigns a ninety day "beyond use" date for refrigerated (b) (4) (b) (4) s), which are further used in the production of sterile finished drug products.

For example,

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- (b) (4) was produced on 02/12/2015; the assigned "beyond use" date is 05/13/2015;
- (b) (4) was produced on 04/12/2015; the assigned "beyond use" date is 07/12/2105;
- (b) (4) was produced on 04/13/2015; the assigned "beyond use" date is 07/12/2015;
- (b) (4) was produced on 02/26/2015; the assigned "beyond use" date is 05/27/2015; and
- (b) (4) was produced on 04/28/2015; the assigned "beyond use" date is 07/27/2015.

OBSERVATION 8

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

Specifically, the firm does not have a stability program for its sterile drug products. The firm has not conducted studies to support the expiry ("beyond use") dates assigned to its sterile drug products. For example, the firm currently assigns thirty day "beyond use" dates to its sterile injectable drug products.

OBSERVATION 9

Each lot of a component that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically, the firm has not established incoming specifications for its active pharmaceutical ingredients that are used in the production of sterile drug products. The firm has not established bacterial endotoxin limits or microbial limits for its active pharmaceutical ingredients that are used in the production of its sterile drug products. For example, prior to the start of this inspection, the firm received and accepted Clonidine HCl USP, Baclofen USP, Bupivacaine Hydrochloride USP, Morphine Sulfate USP, and Hydromorphine Hydrochloride USP based on receiving the suppliers' certificates of analysis. The suppliers' certificates of analysis did not include endotoxin and/or microbial limits. For example,

- Clonidine HCl USP, (b) (4) certificate of analysis does not include bacterial endotoxin limits or microbial limits;
- Baclofen USP (b) (4) 187 certificate of analysis does not include bacterial endotoxin limits or microbial limits;
- Bupivacaine Hydrochloride USP, (b) (4) certificate of analysis does not include microbial limits;

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- Morphine Sulfate USP, (b) (4) certificate of analysis does not include microbial limits; and
- Hydromorphone Hydrochloride USP, (b) (4) certificate of analysis does not include microbial limits.

The five aforementioned APIs are used in production of sterile intrathecal drug products.

OBSERVATION 10

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, the firm has not validated the efficacy of the sterile (b) (4) and (b) (4)) that are used in the cleaning and disinfection of the firm's ISO 5 laminar flow hoods. The firm has not demonstrated these agent's sporicidal abilities.

* **DATES OF INSPECTION:**
05/06/2015(Wed), 05/07/2015(Thu), 05/08/2015(Fri), 05/22/2015(Fri), 06/04/2015(Thu), 06/11/2015(Thu), 07/09/2015(Thu)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."