**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<br>Chicago, IL 60661-4716<br>(312)353-5863 Fax:(312)596-4187 | 1/8/2018-1/26/2018*<br>FEI NUMBER<br>3004504906 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
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<br>Aurora, IL 60506-5649 | TYPE ESTABLISHMENT INSPECTED<br>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 WE OBSERVED:**

## OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

A. Personnel were observed gloving bare hands inside the ISO-5 area prior to engaging in aseptic processing.

Specifically,

On 1/11/2018 we observed the sterile pharmacy technician glove his bare hands under Hood (b) (4) nd clean with (b) (4) and (b) (4) prior to aseptically processing Cyanocobalamin Lot 01112018:31@11 for Prescription (b) (6) The technician did not clean the hood with sporicide prior to compounding. Prescription (b) (6) was dispensed on 1/12/2018.

B. Inadequately or un-protected product intended to be sterile was observed to be exposed to lower than ISO 5 quality air.

Specifically,

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On 01/11/2018, we observed personnel conducting aseptic manipulations that blocked the movement of first pass air around the tip of an uncapped syringe of intrathecal Hydromorphine HCl/Bupivicaine HCl/ Clonidine HCl PF/ (lot #01112018:31@12), after it was filled with (b) (4), sterile product. This lot was used to fill Prescription number (b) (6), dispensed on 1/11/2018.

C. ISO 5 classified areas were not certified under representative dynamic conditions.

Specifically,

Uni-directional airflow was not verified under operational conditions. Smoke studies performed in the ISO5 laminar flow hoods were not performed under dynamic conditions that represent your aseptic processing practices. The dynamic smoke study videos that we viewed demonstrated an operator standing at the far-right side of the hood slightly moving a syringe around. This was not representative of any of the aseptic operations that we observed between 01/08-12/2018. For example, we observed aseptic processing of intrathecal product Hydromorphine HCl/Bupivicaine HCl/ Clonidine HCl PF/ (lot #01112018:31@12), on 01/11/2018, that included the tech sitting in the center of the hood, flipping large syringes in a circular motion, and benches that contained vials, syringes, as well as a trash collection tray.

D. Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically,

Media fill manipulations do not reproduce common, complicated steps observed during aseptic production. For example, we observed intrathecal production involving 60 ml syringes, (b) (4)

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(b) (4), and (b) (4) product exposed to ISO-5 air. However, the Media Fill Test Procedure requires (b) (4) needle changes transferring (b) (4) of media to fill (b) (4) sterile vials. Additionally, your firm's Media Fill Test Procedure does not require the use of a positive control.

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

Specifically,

1. Environmental monitoring was not performed in all aseptic processing areas. On 1/11/18, we observed the pharmacy technician reach into a pass through to obtain a (b) (4) vial for producing B-Complex Lot 01112018:95@7. This pass through is not included in routine cleanroom air sampling or clean room surface sampling. B-Complex Lot 01112018:95@7 was used to fill Prescription (b) (6), dispensed on 1/11/2018.

2. Your firm does not perform viable air and surface monitoring, non-viable particulate monitoring, nor personnel monitoring during every drug production shift in the ISO-5 area. Your firm could not provide documentation assuring that any of these monitoring activities occurring during the production of 1 ML 31G 5/16IN TRIMIX SYRINGE and THIAMINE INJECTION 30 ML.

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

Specifically,

Pressure differentials between ISO-7, ISO-8, and classified areas are not continuously monitored during aseptic production. Your firm management stated that pressure differentials are observed (b) (4).

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G. Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically,

Finished products not confirmed to be free of objectionable microorganisms. For example, your firm management stated that the following drug products were produced and distributed without patient-specific prescriptions, and did not receive any testing prior to release:

1 ML 31G 5/16IN TRIMIX SYRINGE;

THIAMINE INJECTION 30 ML;

PROGESTERONE 100ML PUMPER 20MG/PUMP CRM;

IBUPROFEN TRANSDERM LIPO W/V100ML PUMP [4866] 12% PUMP BTL.

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**OBSERVATION 2**

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

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

Specifically,

Intrathecal products are produced from commercial ingredients that are not indicated for intrathecal use. No endotoxin testing has been performed for intrathecal products with Bupivacaine, Clonidine, or

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Fentanyl. Hydromorphine HCL: Bupivicaine HCL: Clonidine HCL Lot 01112018:31@12 was produced on 1/11/2018 for Prescription (b) (6). Prescription (b) (6) was dispensed on 1/11/2018.

B. Finished product is not tested to evaluate conformance with specifications for potency, sterility, or endotoxins.

Specifically

Your firm management stated that both 1 ML 31G 5/16IN TRIMIX SYRINGE and THIAMINE INJECTION 30 ML were produced and distributed without patient-specific prescriptions, and did not receive any testing prior to release.

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**OBSERVATION 3**

Results of stability testing are not used in determining expiration dates.

Specifically,

Your firm does not have stability data to support assigned "beyond use" dates for drug products. For example, SYRINGE ULTRA *SKINNY*1ML 31G 5/16IN TRIMIX SYRINGE was assigned an BUD of 30 days, however, no stability data exists to support this expiration date.

Your firm management stated that 1 ML 31G 5/16IN TRIMIX SYRINGE was produced and distributed without a patient-specific prescription.

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**OBSERVATION 4**

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There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

Written procedures for production and process controls, for both sterile and non-sterile drug products, produced and distributed without patient-specific prescriptions do not exist. For example, your firm was unable to provide written procedures demonstrating process validation for the following drug products:

1 ML 31G 5/16IN TRIMIX SYRINGE;

THIAMINE INJECTION 30 ML;

PROGESTERONE 100ML PUMPER 20MG/PUMP CRM;

IBUPROFEN TRANSDERM LIPO W/V100ML PUMP [4866] 12% PUMP BTL.

Your firm management stated that these drug products were manufactured and distributed without patient-specific prescriptions.

**OBSERVATION 5**

Batch production and control records are not prepared for each batch of drug product produced.

Specifically,

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For example, your firm stated that 1 ML 31G 5/16IN TRIMIX SYRINGE and THIAMINE INJECTION 30 ML were produced and distributed without patient-specific prescriptions, however, no production log or production documentation were provided.

**OBSERVATION 6**

You produced beta-lactam drugs without providing adequate segregation and cleaning of work surfaces to prevent cross-contamination.

Specifically,

Beta lactam controls do not include data to support that cleaning with (b) (4) water and (b) (4) would be effective in mitigating potential beta lactam residues, if present. For example, Prescription (b) (6) for (b) (4) Capsules of Amoxicillin was dispensed on 7/22/2016 Prescription (b) (6) for (b) (4) Capsules of Cephalexin 500 MG was dispensed on 3/3/2017; both of which were weighed, mixed, and capsulated in non-dedicated hoods. Your firm management stated that these hoods are used for all non-sterile production.

**Annotations to Observations**

Observation 1: Not annotated
Observation 2: Not annotated
Observation 3: Not annotated
Observation 4: Not annotated
Observation 5: Not annotated

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Observation 6: Not annotated

***DATES OF INSPECTION**

1/08/2018(Mon), 1/09/2018(Tue), 1/10/2018(Wed), 1/11/2018(Thu), 1/12/2018(Fri), 1/16/2018(Tue), 1/17/2018(Wed), 1/26/2018(Fri)

X Bryan L Mcguckin
Investigator
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