DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	9/23/2019-10/10/2019*
	FEI NUMBER 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 Aurora, IL 60506-5649	TYPE ESTABLISHMENT INSPECTED 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

Non-microbial contamination was observed in your production area.

Specifically,

While viewing sterile processing on 9/23/2019, black residue was noted on two white plastic garbage cans, one of which was in the ISO 7 cleanroom and the other which was in the ISO 8 anteroom. In addition, some black residue was observed on the far corner of the ISO 7 cleanroom floor.

OBSERVATION 2

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in an area adjacent to the ISO 5 classified aseptic processing area during aseptic production.

Specifically,

During a certification performed for the cleanroom area on 5-23-2018, out of specification results for viable monitoring in one location of the ISO 8 area and four locations in the ISO 7 area occurred. Although cleaning and routine environmental monitoring of the cleanroom resumed, a follow up certification of the cleanroom was not performed until 9-12-2018. Sterile processing occurred on a routine schedule between 5-23-2018 and 9-12-2018.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	James K Ireland, Investigator	X James K Ireland Investigator Signed By: James K. Ireland -S Date Signed: 10-10-2019 09:38:13	10/10/2019

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OBSERVATION 3

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

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. Endotoxin testing is not routinely performed on all processed intrathecal products. Morphine Sulfate PF 30mg/ml Intrathecal lot 09302019:42@12 was produced on 9/30/2019 for prescription (b) (6) . Prescription (b) (6) was dispensed on 9/30/2019.

THIS IS A REPEAT OBSERVATION

OBSERVATION 4

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

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Your firm uses non pharmaceutical grade (b) (4) as a component of non-sterile pharmaceutical products. Dyclonine HCL Oral Dental (Light Mint) ## 1.0% solution lot 10042019:66@2 was produced on 10/4/2019 for prescription number (b) (6). Prescription (b) (6) was dispensed on 10/8/2019.

OBSERVATION 5

Cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, on 9-23-2019, during cleaning of the ISO area, non-sterile wipes were used to clean the ISO 5 hoods.

***DATES OF INSPECTION**

9/23/2019(Mon), 9/24/2019(Tue), 9/25/2019(Wed), 9/26/2019(Thu), 9/27/2019(Fri), 10/07/2019(Mon), 10/08/2019(Tue), 10/09/2019(Wed), 10/10/2019(Thu)

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