DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160 orabioinspectionalcorrespondence@fda.hhs.gov	5/15/2023-5/19/2023 FEI NUMBER 3002808337

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Makoto Hirabuki, Factory Manager

FIRM NAME	STREET ADDRESS
FUJINOMIYA FACTORY OF TERUMO CORP	818, Misonodaira
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fujinomiya, Shizuoka, 418-0004 Japan	Manufacturer

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

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, in-process materials and drug products (b) (4) (b) (4)

Specifically,

a) Review of three batch records for CPDA-1 lot# (b) (4) manufactured on (b) (4) CPD/Optisol lot# (b) (4) manufactured on (b) (4) and CPD/Optisol lot# (b) (4) manufactured on (b) (4) found that (b) (4) testing for (b) (4) cannot be verified (b) (4). For example:

- (b) (4), # (b) (4) (lot # (b) (4)) tested on (b) (4) and (b) (4) # (b) (4) (lot # (b) (4)) tested on (b) (4) used for manufacturing Optisol lot # (b) (4).
- (b) (4), # (b) (4) (lot # (b) (4)) tested on (b) (4), (b) (4) # (b) (4) (lot # (b) (4)) tested on (b) (4) and (b) (4) # (b) (4) (lot # (b) (4)) tested on (b) (4) used for manufacturing CPD lot # (b) (4)

Optisol lot # (b) (4) and CPD lot # (b) (4) were used to prepare TERUFLEX BLOOD BAG SYSTEM with Diversion Blood Sampling Arm CPD/OPTISOL SOLUTION Product Code BB*AGD506A2 lot # (b) (4)

b) Standard operating procedure #CQ040-945B entitled " (b) (4) Test" requires prepared (b) (4) to be used for (b) (4) testing (b) (4) (b) (4) preparation time is not documented for (b) (4) batches manufactured since (b) (4) and (b) (4) use time frame cannot be verified.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Irina Gaberman, Investigator Brandon L Mariner, FDA Center Employee	X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 05-19-2023 09:42:10	5/19/2023

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CITY, STATE, ZIP CODE, COUNTRY Fujinomiya, Shizuoka, 418-0004 Japan	TYPE ESTABLISHMENT INSPECTED Manufacturer

OBSERVATION 2

Written procedures are not followed for the testing and approval of drug product containers.

Specifically,

Your standard operating procedure CQ040-B103, "Final Product/Function Test", requires the blood bags to be (b) (4) at (b) (4) for (b) (4) at (b) (4). On 5/18/2023, the (b) (4) observed displayed on the (b) (4) at the start of the test was (b) (4) and the (b) (4) displayed on the (b) (4) at the end of the test was (b) (4) and did not reach (b) (4) during the blood bag (b) (4) step of your (b) (4) test procedure for CPDA-1 lot# (b) (4). The (b) (4) for this test was recorded on the final release test form (b) (4) as (b) (4) and testing was determined as passing (acceptable).

OBSERVATION 3

Failure to maintain a backup file of data entered into the computer or related system.

Specifically,

Data from the (b) (4) utilized in testing of (b) (4) product prepared in (b) (4), and (b) (4) located in the (b) (4) are not backed up. (b) (4) was used for (b) (4) product testing during manufacturing of CPDA-1 lot# (b) (4) manufactured on (b) (4), CPD/Optisol lot# (b) (4) manufactured on (b) (4) and CPD/Optisol lot# (b) (4) manufactured on (b) (4).

OBSERVATION 4

Records of the inspections of automatic, mechanical or electronic equipment, including computers or related systems are not maintained.

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Specifically,

Your manufacturing is maintained through (b) (4) system (b) (4). Quality Control unit does not have written procedures for frequency of auditing of backup data and does not have a validated method and amount of data they will retrieve and review to ensure that the integrity of the data is maintained.

OBSERVATION 5

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

Specifically,

a) (b) (4) are used to prepare CPD, CPDA-1 and Optisol solutions. These (b) (4) are (b) (4) (b) (4) batch; however, there is no testing/verification performed ensuring that your cleaning procedures were adequately performed.

b) (b) (4) installed to (b) (4) manufactured (b) (4) products CPD, CPDA-1 and Optisol solutions coming from (b) (4) prior to the (b) (4). There is no (b) (4) (b) (4) testing performed to ensure (b) (4).

OBSERVATION 6

Each component is not added to the batch by one person and verified by a second person..

Specifically,

Review of three batch records for CPDA-1 lot# (b) (4) manufactured on (b) (4) CPD/Optisol lot# (b) (4) manufactured on (b) (4) and CPD/Optisol lot# (b) (4) manufactured on

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(b) (4) found that there was no second person verification of addition of components performed as documented in the firm's manufacturing electronic system.

X Brandon L Mariner
FDA Center Employee
Signed By: Brandon L. Mariner -S
Date Signed: 05-19-2023 09:42:54

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EMPLOYEE(S) SIGNATURE
Irina Gaberman, Investigator
Brandon L Mariner, FDA Center Employee

X Irina Gaberman
Investigator
Signed By: 1300222798
Date Signed: 05-19-2023
09:42:10

DATE ISSUED
5/19/2023

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 judgment, 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."