DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	6/2/2025-6/6/2025
	FEI NUMBER 3011999558

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Melissa Merkley, Plasma Center Assistant Manager

FIRM NAME	STREET ADDRESS
Takeda Pharamaceutical Company Limited	478 S Martin St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Longmont, CO 80501-5948	Source Plasma Center

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

Equipment used in the collection and processing of blood and blood components is not standardized and calibrated on a regularly scheduled basis as prescribed in the SOP Manual.

Specifically,

1. On 6/2/2025, I observed employee (b)(6), (b) fail to adequately perform (b)(4) quality control checks on (b)(4) plasmapheresis machines per the firm's SOP and the relevant operator manual entitled, (b)(4) Operator's Manual." Employee (b)(6), (b) performed weigh scale verification of the (b)(4) plasmapheresis machine using calibrated (b)(4) weights that required an additional container to hold the weights and test the weigh scale as stated in the operator's manual. While observing the employee alongside the firm's Quality Lead Tech, I observed employee (b)(6), (b) did not press the "0" or "tare" button after applying the container and before testing the weights. The firm's SOP-243892, (b)(4) Instrument Weigh Scale Verification" instructs in section 3.7 to "touch the [tare] button to tare the weigh scale to zero." This requirement is corroborated by the operator's manual, (b)(4) Operator's Manual" in Chapter 3, section 1(a) which instructs, (b)(4)

2. On 6/4/2025, I performed a record review of the "Verification Report" for the (b)(4) (b)(4) plasma protein refractometer (b)(4) Employee (b)(6), (b) fail to adequately perform the daily (b)(4) quality control check on 5/4/2024. During this review, I discovered record,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	David A Moore, Investigator	X David A Moore Investigator Signed By: 2002807636 Date Signed: 06-06-2025 12:40:41	6/6/2025

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"Verification Report" of a (b) (4) plasma protein refractometer (b) (4) (b) (4) daily serum protein reference control verification test out of range for an (b) (4) test. The manufacturer's user guide entitled, (b) (4) Plasma Protein Refractometer User's Guide" states that after a failed (b) (4) control verification test, the user is instructed to remove the instrument from service and contact a (b) (4) representative for further instruction. The quality control log shows that employee (b) (6), (b) instead tested the refractometer control (b) (4) time resulting in an "in range" level and verified the instrument for use.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
David A Moore, Investigator

X David A Moore
Investigator
Signed By: 2002807636
Date Signed: 06-06-2025
12:40:41

DATE ISSUED
6/6/2025

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."