DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/ Division of Biotechnology Manufacturing 10903 New Hampshire Avenue; White Oak Building 51, Room 2269 Silver Spring, MD 20993 E-mail: OPMABLAInspection483Responses@fda.hhs.gov	04/27/2026-05/05/2026
	FEI NUMBER 3035338829

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Selva Ganesan, General Manager, Singapore Site

FIRM NAME	STREET ADDRESS
Thermo Fisher Biopharma Services PTE. LTD (TFBS)	31 Joo Koon Circle
CITY, STATE, ZIP CODE, COUNTRY Singapore 629108	TYPE ESTABLISHMENT INSPECTED Drug product 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

The visual inspection program for (b) (4) drug product (b) (4) manufactured at the TFBS facility is inadequate. Specifically:

A. Defects identified during 100% visual inspection, including those with the potential to compromise container closure integrity and product sterility, have not been adequately trended or investigated to determine root causes and implement appropriate corrective and preventive actions (CAPAs).

i. A significant upward trend in the percentage of particulate defects has been observed from the engineering batch through the process performance qualification (PPQ) batches. These particles—including white particles, white fibers, and colored particles—are categorized by your firm as critical defects. The observed increase in particulate contamination has not been investigated.

(b) (4)

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
SEE REVERSE OF THIS PAGE	Madushini N. Dharmasena -S Digitally signed by Madushini N. Dharmasena -S Date: 2026.05.04 21:49:41 -04'00' YING ZHANG -S Digitally signed by YING ZHANG -S Date: 2026.05.04 21:46:01 -04'00'	**Madushini Dharmasena**, Ph.D., Supervisory Pharmaceutical Scientist (acting) CDER/OPQ/OPMA/DPMAVI **Ying Zhang**, Ph.D., Supervisory Chemist, CDER/OPQ/OPMA/DPMAI	05/05/2026

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B. A recurring container defect, identified as a "Check," was observed at a significant frequency during the second PPQ campaign. This defect is categorized as major (length ≥(b) (4) mm) or minor (length between(b) (4) mm and(b) (4) mm). Despite its recurrence, this defect has not been investigated to determine its root cause.

(b) (4)

C. Multiple batches(b) (4) out of(b) (4)have failed to meet the established Acceptable Quality Limit (AQL) for critical defects, which your procedure SOP-000521068 states have an acceptance number of (b) (4) The recurrence of these failures demonstrates the deficiencies in the visual inspection program.

(b) (4)

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SEE REVERSE OF THIS PAGE	Madushini N. Dharmasena -S Digitally signed by Madushini N. Dharmasena -S Date: 2026.05.04 21:50:17 -04'00' YING ZHANG -S Digitally signed by YING ZHANG -S Date: 2026.05.04 21:46:44 -04'00'	**Madushini Dharmasena**, Ph.D., Supervisory Pharmaceutical Scientist (acting) CDER/OPQ/OPMA/DPMAVI **Ying Zhang**, Ph.D., Supervisory Chemist, CDER/OPQ/OPMA/DPMAI	05/05/2026

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OBSERVATION 2

Your manufacturing process for (b) (4) drug product is not consistently producing a product that meets its established specifications. This is evidenced by a significant number of batch rejections, process deviations, and invalidated qualification runs.

A. (b) (4) out of the (b) (4) drug product PPQ batches manufactured to date have been rejected.

(b) (4)

B. Your Aseptic Process Simulations (APS), intended to qualify your aseptic process, have been repeatedly invalidated or aborted due to process failures, including media leakage (QR#1019604), breakage of vials (QR#1067037), and atypical rejects at the stopper inspection station (QR#1272483).

C. The manufacturing of a post-PPQ batch was delayed on April 28 due to a malfunction of the particle monitoring system. Manufacturing of this batch did not resume until April 29.

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