DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	11/10/2025-11/14/2025
	FEI NUMBER 3007164129

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Lo Suan Theng, Site Head

FIRM NAME	STREET ADDRESS
Roche Singapore Technical Operations Pte. Ltd.	10 Tuas Bay Link
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Singapore, 637394 Singapore	API 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 I OBSERVED:

Procedures applicable to the quality unit are not adequately written and followed.

Specifically,

QE-177112 documents that on 29SEP25, the maintenance technician found a damaged (b) (4) and replaced it during inspection of (b) (4) on (b) (4) per WO (b) (4). During WO w on 10OCT25 (11 days later), the engineer noted the (b) (4) belonged to process contacting equipment and initiated a Quality Event. Per SOP-02488, section (b) (4) states "When repairing or replacing process contacting equipment/instruments/parts due to physical damage" evaluation per SOP-0121060 needs to be made. SOP-0121060, Event Management Process, states to "Document any events in the Veeva Vault QMS within (b) (4) of detecting the Event". Additionally there is no time limits established for review of Work Orders with potential impact to GMP systems.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jeffrey D Meng, Investigator	DATE ISSUED 11/14/2025

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."