DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Pkwy Alameda, CA 94502 CDER-OC-OMQ-Domestic483Response@fda.hhs.gov	06/08/2026-06/12/2026 FEI NUMBER 3026501935

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Kevin G. Beatty, President

FIRM NAME	STREET ADDRESS
Paragon Swiss	545 Aldo Ave. Ste 1
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Santa Clara, CA 95054	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 WE OBSERVED:
Quality System

OBSERVATION 1
Failure of your quality unit to conduct Annual Product Quality Review (APQR) annually.

Specifically,

Your firm failed to follow your established written procedure, SOP-033, *Annual Product Quality Review (AQPR)*, Rev B.0, Effective Date: 2024-10-02.

A. Your firm failed to conduct APQRs for the API (b) (4) (approximately (b) (4) lots manufactured in 2024); (approximately (b) (4) lots manufactured in 2025). Section 6.1 of SOP -033 states, "Regular quality review of … (b) (4) should be conducted with the objective of verifying the consistency of the process. Such review should be conducted and documented annually." Additionally, this SOP fails to establish a deadline requirement for timely APQR review and approval.

B. Your firm failed to review relevant data of the process and analytical method results of stability monitoring programs for APQR as required per SOP-033.

   Section 5.2 of SOP-033 states, "Quality Unit shall ensure be responsible for the collection of relevant data and information required for preparing the Annual Product Quality Review."

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Nathan E. Hellman, CSO Gunneet Kaur, CSO	06/12/2026

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Section 6.2.4 of SOP-033 states, "A review of any changes carried out to the processes and analytical methods*."

Section 6.2.5 of SOP-033 states, "A review of the results of the stability monitoring programs*."

On June 9, 2026, your firm's President stated that no review was conducted.

OBSERVATION 2

Your firm failed to establish written procedures for the active pharmaceutical ingredient (API), (b) (4) .

Specifically,

A. Your firm lacks a written recall procedure in place to facilitate the rapid and effective recall of any API lot that may be found to be defective or potentially harmful.

B. Your firm lacks an equipment requalification procedure.

This is a repeat observation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Gunneet Kaur	Nathan E. Hellman, CSO Gunneet Kaur, CSO	06/12/2026

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."