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	12/17/2025-12/19/2025
	FEI NUMBER 3008676264

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Ismael Valverde, PhD/MBA, Vice President GMP Labs

FIRM NAME	STREET ADDRESS
PPD Development Ireland Ltd.	Building C, Garrycastle Business And Technology Park
CITY, STATE, ZIP CODE, COUNTRY Athlone, Co. WESTMEATH Ireland	TYPE ESTABLISHMENT INSPECTED Contract Laboratory Testing

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 responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

A. You failed to follow written testing program for assessing the stability characteristics of drug substance and drug product as defined in your client's stability protocols, which requires completion of stability testing within (b) (4) of the scheduled testing date.

From 2019 through 2025, you initiated a total of 58 deviations initiated regarding missed stability testing windows, which delays ranging from (b) (4) beyond the required time frame. These deviations include, but are not limited to:

i. Deviation 104423, initiated on February 3, 2022, documented the error to be insufficient method detail and operator oversight, which impacted the stability testing date to be delayed by (b) (4) This impacted 9 drug substance and drug product stability samples, stability, under conditions (b) (4)
(b) (4)

ii. Deviation 135887, initiated on October 13, 2022, documented the error to be improper equipment maintenance due to failure to follow SOP and training gaps, which caused the stability testing date to be delayed by (b) (4) This impacted (b) (4) drug product stability

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Peng Zhou, Investigator Thai D Truong, Investigator	X Peng Zhou Investigator Signed By: 2002104595 Date Signed: 12-19-2025 05:36:33	12/19/2025

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samples, at (b) (4) (b) (4)

iii. Deviation 237071, initiated on February 24, 2025, documented the error to be supervisor scheduling error and incorrect prioritization, which caused the stability testing date to be delayed by (b) (4) This impacted (b) (4) drug substance stability sample, at (b) (4) (b) (4)

iv. Deviation 238332, initiated on March 3, 2025, documented the error to be supervisor scheduling error, equipment failure, and incorrect prioritization of other high priority projects, which caused the stability testing date to be delayed by (b) (4) This impacted (b) (4) drug product stability sample, under stability condition (b) (4)

v. Deviation 84802, initiated on October 19, 2021, documented the error to be operator execution error and delayed secondary data, which caused the stability testing date to be delayed by (b) (4) This impacted (b) (4) licensed drug substance stability sample, (b) (4) (b) (4)

vi. Deviation 53847, initiated on December 4, 2019, documented the error to be operator oversight, which caused the stability testing date to be delayed by (b) (4) This impacted (b) (4) licensed drug substance stability samples, at (b) (4)

B. Between March 18, 2019, and December 20, 2023, you initiated 19 Corrective and Preventive Actions (CAPAs) to address missing stability testing windows for drug substance and drug product. Despite these corrective measures, missing stability testing windows

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continued to occur throughout the extended period from March 18, 2019, to March 3, 2025, with a total of 58 documented occurrences.

Year	Number of Occurrences
2019	23
2020	16
2021	13
2022	1
2023	2
2024	1
2025	2

C. SOP-17197 FORM-03217 v5.0 establishes that for (b) (4) laboratory methods, (b) (4) is optional, and (b) (4) (b) (4) You applied this (b) (4) complexity classification to quality control testing methods and data processing/evaluation for release testing of drug substances and drug products without providing adequate comprehensive hands-on training, including

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(b) (4)

(b) (4)

(b) (4)

(b) (4)

Between 2019 and 2025, operator-related errors accounted for approximately 61% of deviations associated with CBER-licensed products, including protocol noncompliance, method or monograph deviations, documenting errors, and reporting inaccuracies.

X _____

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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."