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	04/17/2023-04/21/2023
	FEI NUMBER 3003909356

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jacques Marbehant, MScEng, Senior Vice President, Head of Manufacturing Eng & HSE

FIRM NAME	STREET ADDRESS
UCB Pharma SA, Braine	Chemin du Foriest
CITY, STATE, ZIP CODE, COUNTRY Braine-l'Alleud, Belgium, 1420	TYPE ESTABLISHMENT INSPECTED Drug Product

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

Your Quality Unit failed to establish adequate document control of the forms that are used for GMP activities. Specifically,

a. Uncontrolled blank forms have been used for the in-process sample logs that are attached to the production master records.
b. Uncontrolled facility cleaning logs are used to record cleaning activities of classified areas.
c. Uncontrol[(b) (4)] ecklist de vérification et de libération des dossiers de lot de remplissage (seringues [(b) (4)] Sop-af-104853, version 1.0, is used by the Qualified Person for batch release.

Shredded material was observed on April 19 and 21 in Building [(b) (4)] office area. The shredded material of April 21 contained referenced to SOP-af-001086, fréquence de test de remplacements des filtres, and mentioned Point [(b) (4)] [(b) (4)] [(b) (4)] in room [(b) (4)] in Building [(b) (4)] There is no assurance that the shredded material did not contain quality documents.

OBSERVATION 2

The environmental and personnel monitoring are inadequate in classified areas.

a. Swab sampling after filling of [(b) (4)] yringes in the RABS is inadequate. For example, only [(b) (4)] are swabbed after manufacturing. The stopper contact surfaces such as stopper [(b) (4)] stoppe [(b) (4)] stopper [(b) (4)] [(b) (4)] support, stoppering handling and [(b) (4)] [(b) (4)] [(b) (4)] support and [(b) (4)] are not swabbed after manufacturing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Madushini N Dharmasena -S Hamet M. Toure -S Digitally signed by Hamet M. Toure -S Date: 2023.04.21 11:09:36 -04'00' Alice S. Tsao -S Digitally signed by Alice S. Tsao -S Date: 2023.04.21 11:15:39 -04'00'	Madushini Dharmasena, Ph.D., Senior Pharmaceutical Quality Assessor Hamet Touré, PharmD MPH, Regulatory Officer Alice Tsao, Consumer Safety Officer	04/21/2023

b. The personnel monitoring limits established for operators performing operations in the [redacted] RABS are inadequate to meet acceptance criteria for Grade A (ISO 5). During the filling operation set up on April 19, 2023, the operator's entire upper body moved inside the RABS. However, as per SOP 016330 V18.0 and SOP 015731 V1.0, only operator's right and left hand finger monitoring limits meet Grade A acceptance criteria. The grade A operator's lower forearm, chest and hood monitoring limits meet the requirements for Grade B (ISO 7).

OBSERVATION 3
Your procedures are inadequate to describe the handling and rejection of in-process materials. Specifically,

Your procedure SOP-004943, Version 11.0, Main Warehouses: Management of Rejected Items and Returns to Supplier, fails to address the handling and rejection of in-process materials. SOP-004836, Version 8.0, Destruction of Goods on Braine Site, does not require the rejection of materials prior to issuance of destruction work orders.

During the walkthrough of the [redacted] warehouse on April 17, 2023, the following in-process materials were stored in a locked cage labeled as rejected when they had a quarantined status in your firm's SAP system. These materials are pending for destruction.

- [redacted] Tablets, [redacted] mg, Material# [redacted] Batch# [redacted]
- [redacted] Tablets, [redacted] mg, Material# [redacted], Batch# [redacted]

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."