DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Biotechnology Manufacturing 10903 New Hampshire Avenue; White Oak Building 51, Room 2269, Silver Spring, MD 20993 Email: OPFBLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	01/27/2022 - 02/04/2022 FEI NUMBER 3003909356

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Jacques Marbehant, Head of Global Quality

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

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DURING AN INSPECTION OF YOUR FIRM ~~I~~ (WE) OBSERVED:

Observation 1

Failure to establish process controls designed to assure that the drug product you manufacture has the identity, strength, quality, and purity that it purports or is represented to posses. Specifically,

a. On 31 January 2022, I (WS) observed the dripping of fill (b) (4) [redacted] on the restrictive access barrier (RAB) fill line (b) (4) [redacted] in (b) (4) [redacted] manufacture for Lot (b) (4) [redacted] when in static mode, with the fill (b) (4) [redacted] observed (b) (4) [redacted] with a sterile (b) (4) [redacted] wipe to remove excess drug product in mitigation of product within the stopper (b) (4) [redacted] In dynamic mode, the cycling of (b) (4) [redacted] into the filling zone approximately (b) (4) [redacted] a droplet of product was frequently observed at the fill (b) (4) [redacted] tips at the start of filling. There is no quality assessment to evaluate the use of sterile (b) (4) [redacted] in manufacture and the impact on (b) (4) [redacted] drug product quality. For Lot (b) (4) [redacted] you did not demonstrate that the filling process for the drug product was under control to ensure the prevention of contamination of (b) (4) [redacted] drug product by equipment that could reasonably be expected to have an adverse effect on product quality.

b. In the setup of the fill line, the (b) (4) [redacted] sterile fill (b) (4) [redacted] may be (b) (4) [redacted] and sanitized with sterile (b) (4) [redacted] The process of sanitization of critical surfaces should not be justified based on inadequate aseptic technique.

c. Observed during the RAB fill line setup and manufacturing process for (b) (4) [redacted] drug product Lot (b) (4) [redacted] was the inadequate fitting of the gown hood and mask to the face, allowing for exposed skin to be present.

d. There is no media fill procedural requirement or validation to evaluate the sterile hold time of (b) (4) [redacted] for the filling machine setup equipment to assess the worst-case manufacturing process.

Observation 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Wayne Seifert Roger F. Zabinski	Wayne Seifert, Consumer Safety Officer Roger Zabinski, Consumer Safety Officer	02/04/2022

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Control procedures are not established which monitor the output of those manufacturing processes that may be responsible for causing variability in the characteristic of in-process material and the drug product. Specifically,

a. SOP-ai-101286, Processus de qualification au mirage, v4, Effective date 03 May 2021 describes the qualification of visual inspectors. In the visual inspection process, particles including unembedded within the drug product have an overall reject limit. Unless exceeded, there is no deviation or investigation, with the rejected drug product units discarded without QA/QC oversight. There is no training of the visual inspectors on the criticality of an extrinsic particle nor does SOP-ai-101826 or any other procedure defining inherent, intrinsic or extrinsic, with an extrinsic particle potentially have an impact on the sterility assurance of the product. Furthermore, product found in the stopper (b) (4) [redacted] for (b) (4) [redacted] manufacture are acceptable units for release.

b. Equipment for manufacture is cleaned by part washer LAV-3201, with (b) (4) [redacted] dispensed by pump at a fixed RPM based on time, not conductivity. Neither the pump RPM nor volume dispensed based on time are calibrated or verified, respectively for conformance to a specification at any interval.

Observation 3

A utility is of inadequate design. Specifically,

On 28 January 2022, the (b) (4) [redacted] DST-3003 was observed with multiple lines extending into a tank of (b) (4) [redacted] uncontrolled (b) (4) [redacted] that included (b) (4) [redacted] lines. The (b) (4) [redacted] lines do not have a mechanical device or (b) (4) [redacted] to prevent back siphonage.

Observation 4

A facility is not adequately maintained. Specifically,

On 27 January 2022, we (WS and RZ) observed within Building (b) (4) [redacted] CNC space, room 107 and room 01.183, visitor personnel access (b) (4) [redacted] and hand washing area, respectively, with deteriorated sealant at the wall ceiling (b) (4) [redacted] interface.

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