DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. F.D.A., CDER/OPQ/OPF/Division of Biotechnology Manufacturing 10903 New Hampshire Avenue,Building 51, Rm. 2269 Silver [redacted], Maryland 20903 OPM [redacted]nspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	February 7 - 11, 2022 **FEI NUMBER** 3002806849

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael Isele, Managing Director

FIRM NAME	STREET ADDRESS
Wasserburg Arneimittelwek GmbH (Recipharm)	Herderstrasse 2
CITY, STATE AND ZIP CODE	**TYPE OF ESTABLISHMENT INSPECTED**
Wasserburg a. Inn, Germany 83512	Drug Product 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) (WE) OBSERVED:

1. Standard Operating Procedures are not followed or are not adequate in the description of operations. Specifically,

A. On Tuesday, February 8, 2022, during filling activities in Bldg. [redacted] Production Area [redacted] Filling Line [redacted] (Rm. [redacted] the [redacted] gloves in front of the [redacted] were used ambidextrously. Following the fill, during environmental monitoring activities, these [redacted] gloves were only monitored on one side of the gloves. The SOP's do not direct the sampling of the [redacted] gloves for both sides when the glove is used in production activities ambidextrously. SOP A-008814, ver. 14.0, effective date April 23, 2021, Monitoring/Mikrobiologie: Bemusterung von Oberflächen, and SOP A-008921, ver. 21, Attachment 7.1.3, effective date January 19, 2018, Monitoring/Mikrobioligie: Oberflächenkeimzahl-Geräte, Maschinen und Räume, describes the procedure and locations for environmental monitoring in Grade A area, that includes the monitoring of [redacted] gloves, do not describe ambidextrous monitoring of [redacted] gloves.

B. On Tuesday, February 8, 2022, in Bldg. [redacted] Production Area [redacted] Filling Line [redacted] Rm. [redacted] during the set up activities for filling, [redacted] wipes were used to wipe down materials prior to placing them in the [redacted] (e.g. [redacted] During the sanitization of these [redacted] the [redacted] wipes were never folded after each wipe stroke and the soiled side of the wipe was further used. The Senior Manager of Compliance stated that folding of [redacted] wipes is not described in any of SOPs regarding sanitizing objects prior to placing them into the [redacted]

C. On Tuesday, February 8, 2022, in Bldg. [redacted] Production Area [redacted] Filling Line [redacted] (Rm. [redacted] during set up activities of the filling line, EM plates were placed in the transfer area that feeds the [redacted] vials to the [redacted] When the operator opening the [redacted] into Grade B, the Grade A side of the [redacted] was not sanitized prior to closing. SOP A 064805, ver. 05, November 24, 2021, Vorbereitung und Durchführung von mikrobiologischen Umgebungskontrollen bei Abfüllung auf [redacted] does not describe sanitization of the [redacted] prior to closing back into Grade A after it has been opened into Grade B.

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
SEE REVERSE OF THIS PAGE	Michael R. Shanks -S Digitally signed by Michael R. Shanks -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001408317, cn=Michael R. Shanks -S Date: 2022.02.11 08:54:09 -05'00' Unnee Ranjan -S Digitally signed by Unnee Ranjan -S Date: 2022.02.11 15:59:31 +01'00'	Michael Shanks, Biologist Unnee Ranjan, Consumer Safety Officer	02/11/2022

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U.S. F.D.A., CDER/OPQ/OPF/Division of Biotechnology Manufacturing 10903 New Hampshire Avenue,Building 51, Rm. 2269 Silver Spring, Maryland 20903 OPM (b) (4) nspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	February 7 - 11, 2022
	FEI NUMBER 3002806849

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael Isele, Managing Director

FIRM NAME	STREET ADDRESS
Wasserburg Arneimittelwek GmbH (Recipharm)	Herderstrasse 2
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D. On Monday, February 7, 2022, in Bldg. (b) (4) Room (b) (4) an area used to store quarantine and released API, development bottles of (b) (4) which were not quarantine or release GMP API, were noted in one of the Quarantine/Released freezers. The Sr. Manager Regulatory Affairs stated that an SOP for handling of non-GMP material is not currently available.

E. On Tuesday, February 8, 2022, in Bldg. (b) (4) Production Area (b) (4) Filling Line (b) (4) (Rm. (b) (4) during fill operations, two process waste bottles used during filling, one inside the (b) (4) and one outside of the (b) (4) were noted as "not labeled." Additionally, on Thursday February 10, 2022, a cart with multiple (b) (4) on it was noted in the Production Area (b) (4) Grade D corridor. Neither the (b) (4) or the cart were labeled for status. SOP A 0096, ver. 12, September 1, 2020, Reinung, Geräte für Ansatz und Abfüllung, is deficient in describing the labeling of these items.

F. On Thursday, February 8, 2022, a Grade D operator was observed in (b) (4) (Rm. (b) (4) and was standing on the Grade C (Compounding Rm.) side of the (b) (4) This room has no demarcation line or way to separate Grade D and Grade C operators. SOP 022403, ver. 3.0, effective date April 5, 2017, Umwandlung von Geräten, Behältern und Rohstoffgebinden: Zonenwechsel von D (Produktionsbereich) nach C (Ansatzraum) is deficient in describing the segregation of Grade C and Grade D operators in this area.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Michael R. Shanks -S Digitally signed by Michael R. Shanks -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001408317, cn=Michael R. Shanks -S Date: 2022.02.11 10:02:27 -05'00'	Michael Shanks, Biologist	
	Unnee Ranjan -S Digitally signed by Unnee Ranjan -S Date: 2022.02.11 16:00:13 +01'00'	Unnee Ranjan, Consumer Safety Officer	02/11/2022