DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Prajakta Varadkar Telephone: 240-402-7439 Industry Information: www.fda.gov/oc/industry	11/29/2023-12/05/2023
	FEI NUMBER 3003433722

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Tilman C. Rock , Site head Biopharma, Austria

FIRM NAME	STREET ADDRESS
Boehringer Ingelheim RCV GmbH & Co KG	Dr. Boehringer-Gasse 5-11
CITY, STATE AND ZIP CODE 1121 Vienna, Austria	TYPE OF ESTABLISHMENT INSPECTED 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. SOP for critical steps in shipping is inadequate. Specifically, BI-RCV SOP 033-AA-VS-01719 "Packing Product (b) (4) for Shipping" does not describe the duration in which the drug substance final containers need to be loaded in the (b) (4). In addition, the SOP lacks instructions on the activation of RCV (b) (4) final container.

2. Equipment preventive maintenance is not adequate to prevent frequent malfunction. Specifically, seal leaks were found on the final container bottle head tubing of three DS batches (Batch # (b) (4), (b) (4), and (b) (4)) after sealing (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	/S/	Prajakta Varadhar, Biological Reviewer Pete Amin, Consumer Safety Officer	12-5-2023

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 judgement, 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."