DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Pharmaceutical Manufacturing Assessment 10903 New Hampshire Avenue; White Oak Building 51, Room 2269, Silver Spring, MD 20993 Email: OPMABLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	08/19/2024 - 08/27/2024
	FEI NUMBER 3002806419

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Remi Helmig, Senior Plant Director, Plant Management

FIRM NAME	STREET ADDRESS
Baxter Oncology GmbH	Kanstrasse 2
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Halle Westfalen, North-Rhine - Westphalia 33790	Drug Product Manufacturer

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

Observation 1: Failure to establish process, procedural controls and testing designed to assure that the drug products you manufacture have the identity, strength, quality and purity that it purports or is represented to possess. Specifically,

a. You failed to conduct aseptic process simulation, a media challenge representative of your manufacturing process. Your manufacturing process for the (b) (4) filling line includes (b) (4) used as a product vial (b) (4) in the drug product filling process, U.S. commercial product (b) (4) In aseptic process simulation, you (b) (4) You further fail to (b) (4) to the fill line.

A procedure is deficient as (b) (4) with only the (b) (4) active in the aseptic process simulation. Specifically, procedure (b) (4) "Validation Instruction, Validation of Aseptic Process (Media Fills)", Section (b) (4) (b) (4) specifies: (b) (4)

The aseptic process simulation deficiency extends to drug product fill lines (b) (4) products for U.S. distribution (b) (4)

b. There is no requirement to include the vials held in the (b) (4) up to (b) (4) sterile hold in the (b) (4) aseptic process simulation program.

A procedure is deficient as (b) (4) "Risk Assessment Validation Concept Process (Media Fills)" identifies vials processed after (b) (4) are within a (b) (4) with the impact on sterility of the (b) (4) (sterile hold) excluded from the aseptic process simulation based on system control mechanisms.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Wayne Seifert Sudipan Karmaker. Bingchen Du	Wayne Seifert, Senior Consumer Safety Officer Sudipan Karmaker, Sr. Pharm Quality Assessor Bingchen Du, Pharmaceutical Scientist	08/27/2024

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c. You were unable to manufacture without the formation of drug product droplets and dripping from the (b) (4) (b) (4) product (b) (4) . Batch (b) (4) on the (b) (4) filling line (b) (4) Your drug product filling process has not been optimized, a sterility assurance concern.

d. You failed to provide evidence for the (b) (4) drug product that residual (b) (4) from the (b) (4) filling line sanitization does not have a product degradation effect, supportive of long-term drug product stability.

Observation 2: Calibrations to a specification in support of (b) (4) drug product manufacture are not available. Specifically,

a. You fail to calibrate the drug product (b) (4) (asset (b) (4) track speed at any frequency.

b. You fail to calibrate the drug product (b) (4) asset (b) (4) (b) (4) (b) (4) at any frequency.

Observation 3: The (b) (4) drug substance (DS) storage requirement is unclear. Specifically,

The (b) (4) DS was observed labeled with two storage conditions, 2 - 8°C and (b) (4) °C. Furthermore, the (b) (4) (b) (4) DS label specifies (b) (4) On 19 August 2024, the DS was observed stored within the 2 - 8°C walk-in (b) (4) not under restrictive (b) (4) conditions.

Observation 4: A validation in support of (b) (4) drug product manufacture is deficient. Specifically,

(b) (4) used in sterilization of (b) (4) filling line equipment and components fails to have a validation and routine revalidation for the air vent filter sterilization, physical and biological assessment.

Observation 5: Standard operating procedures (SOP) supporting manufacture of (b) (4) drug product are deficient or are not followed. Specifically,

a. During assembly of the stoppering system to the (b) (4) filling line (RABS) on (b) (4) operator

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arms were observed below their waist level in Grade B space. Standard Operating Procedure (b) (4) "Verfahrensanweisung Aseptische Herstellung in der Pharmaproduction", Effective 18 August 2024, fails to describe the good clean room behavior, having arms maintained at waist level.

b. You qualified and validated the (b) (4) tester for audit trail. According to (b) (4) "Audit Trail Review Baxter Oncology", Effective date 16 August 2024, Section 6, Audit Trail Review specifies that audit trail review is part of the routine data review/approval process. The audit trail associated with data should be reviewed with (b) (4) and before (b) (4) of the record. You fail to review the (b) (4) tester audit trail at any frequency.

c. Per (b) (4) "Access Control to Halle Site", GMP manufacturing space access control is integrated into the employee ID via Tisoware PLUS, with the system failing to track when a revocation of access rights is performed based on personnel qualification status.

Observation 6: Facilities and equipment in support of (b) (4) drug product manufacture are not adequately maintained. Specifically,

a. Observed in (b) (4) area (b) (4) and equipment cleaning and sterilization area (b) (4) was deteriorated ceiling and wall interface sealant. Area (b) (4) was observed with a light fixture lens in a deteriorated state. (b) (4) tanks (b) (4) (b) (4) liters) and (b) (4) (b) (4) liters) were observed with the (b) (4) tube and spray device in a deteriorated state. You fail to have a rouge management procedure.

b. Trolleys located in the GMP warehouse and used in the intermediate storage of labels and used (b) (4) were observed in an unkept state.

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