DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	10/27/2025-11/26/2025* FEI NUMBER 3012385969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hassan M. Zain, Interim Site Head

FIRM NAME	STREET ADDRESS
BAXALTA US INC.	25212 W Il Route 120
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Round Lake, IL 60073-9610	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 WE OBSERVED:

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not fully followed.

A. Since October 31, 2022, there have been at least (b) (4) false positive (b) (4) recoveries on (b) (4) days from samples taken from the Flexbumin manufacturing area, with the most recent recovered on August 29, 2025. Handling of these recoveries is deficient as follows:

i. There is no assurance that the presence of (b) (4) can be detected as the (b) (4) analytical methods employed by the contracted laboratory can only detect (b) (4).

ii. When there is a (b) (4) recovery by the (b) (4) method, the positive result is invalidated by confirmatory testing conducted by an (b) (4) method, whose results become the test of record. As a result, there is no evaluation of potential impact of the presence of (b) (4). For example:

Recoveries (b) (4) of (b) (4) on Augst 21, 2024	Number of Samples Sites Recovered with False Positive Results
(b) (4) (b) (4)	(b) (4) (b) (4)
Recoveries (b) (4) (b) (4) on May 23, 2025	Number of Samples Sites Recovered with False Positive Results
(b) (4)	(b) (4)
Recoveries After HEPA Filter	Number of Sample Sites Recovered with False

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Peng Zhou, Investigator Shafiq Ahadi, Investigator X Peng Zhou Investigator Signed By: 2002104595 Date Signed: 11-26-2025 12:30:47	11/26/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	10/27/2025-11/26/2025* FEI NUMBER 3012385969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hassan M. Zain, Interim Site Head

FIRM NAME	STREET ADDRESS
BAXALTA US INC.	25212 W Il Route 120
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Round Lake, IL 60073-9610	Manufacturer

(b) (4) on June 10, 2025	Positive Results
(b) (4)	(b) (4)
Recoveries (b) (4)	Number of Sample Sites Recovered with False
(b) (4) on June 13, 2025	Positive Results
(b) (4)	(b) (4)
(b) (4)	(b) (4)
(b) (4)	(b) (4)
(b) (4)	(b) (4)

B. You failed to perform investigations and evaluate the impact of at least (b) (4) false positives (b) (4) recoveries inside your manufacturing areas between September 15, 2022 to October 27, 2025, during which over (b) (4) lots of Flexbumin were manufactured, including (b) (4) lots of Flexbumin for the US market.

C. Per (b) (4) "Risk Analysis- Prevention of Cross-Contamination- (b) (4), you have concluded that your cross-contamination risk is improbable regarding materials and materials flow, utilities, personnel and documentation flow, and facilities and equipment. Considering you are (b) (4) (b) (4), the following deficiencies have been found in your risk assessments to date:

i. You have a limited testing scope for (b) (4) detection in that samples are only taken at (b) (4) of manufacturing suites, (b) (4) areas, and (b) (4) areas. You do not test for the presence of (b) (4) in critical areas such as (b) (4) the manufacturing suite, packaging areas, warehouse, (b) (4), or finished product packaging.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	10/27/2025-11/26/2025* FEI NUMBER 3012385969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Hassan M. Zain, Interim Site Head	
FIRM NAME BAXALTA US INC.	STREET ADDRESS 25212 W Il Route 120
CITY, STATE, ZIP CODE, COUNTRY Round Lake, IL 60073-9610	TYPE ESTABLISHMENT INSPECTED Manufacturer

ii. Prior to August 2025, you had not considered that (b) (4) areas in both the (b) (4) (b) (4) areas, including (b) (4) Flexbumin manufacturing processes and the (b) (4) room, did not have (b) (4) (b) (4).

iii. To date, you have not track personnel movement between (b) (4) (b) (4) areas. Personnel from (b) (4) areas transited the (b) (4) prior to entering manufacturing suites and warehouses located in the (b) (4) (b) (4) areas, including Flexbumin manufacturing areas. Personnel from (b) (4) (b) (4) areas shared the (b) (4) prior to August 21, 2024.

iv. Personnel monitoring for (b) (4) of your personnel, as well as personnel from the (b) (4) (b) (4) firm, who enter Flexbumin manufacturing areas, including manufacturing suites (Grade (b) (4) and the (b) (4) area), is not conducted.

v. Prior to June 13, 2025, you had not evaluated the (b) (4) for the (b) (4) located in the (b) (4) for Production Line (b) (4), which is accessible from the (b) (4) areas. The (b) (4) is used in the manufacturing process of Flexbumin. The entry from the (b) (4) has been sealed on June 13, 2025.

vi. Prior to June 4, 2025, the (b) (4) air for the (b) (4) had not been tested for presence of (b) (4). The (b) (4) is used for the cleaning of (b) (4) (b) (4) used in Flexbumin production.

vii. You have not evaluated the risk of cleaning agents being received in the (b) (4) (b) (4) and then transported to a (b) (4) located in

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	10/27/2025-11/26/2025* FEI NUMBER 3012385969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Hassan M. Zain, Interim Site Head	
FIRM NAME BAXALTA US INC.	STREET ADDRESS 25212 W Il Route 120
CITY, STATE, ZIP CODE, COUNTRY Round Lake, IL 60073-9610	TYPE ESTABLISHMENT INSPECTED Manufacturer

(b) (4) area. For example: (b) (4), which are used in (b) (4) of the (b) (4) utilized to hold Flexbumin bulk drug (b) (4), were first received by the (b) (4) prior to August 21, 2024.

viii. There was (b) (4) in the (b) (4) areas prior to complete separation on June 13, 2025.

vix. (b) (4) copies of quality control testing paperwork from the (b) (4) (b) (4) were delivered to your Quality personnel located on the (b) (4) until (b) (4) on August 21, 2024.

x. Prior to May 23, 2025, the risk of (b) (4) was not evaluated in the (b) (4) Flexbumin manufacturing areas.

D. You have not evaluated risk regarding batches released prior to (b) (4) changes, including:
i. (b) (4) of (b) (4) on August 21, 2024
ii. (b) (4) on May 23, 2025
iii. HEPA Filter (b) (4) on June 10, 2025
iv. (b) (4) on June 13, 2025

OBSERVATION 2
There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	10/27/2025-11/26/2025* FEI NUMBER 3012385969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hassan M. Zain, Interim Site Head

FIRM NAME	STREET ADDRESS
BAXALTA US INC.	25212 W Il Route 120
CITY, STATE, ZIP CODE, COUNTRY Round Lake, IL 60073-9610	TYPE ESTABLISHMENT INSPECTED Manufacturer

A. Despite having suspected and confirmed (b) (4) recoveries in the (b) (4), which is transited by your manufacturing personnel (b) (4) your GMP areas, you issued (b) (4) (b) (4) on January 11, 2025, to justify continued manufacturing without performing investigations and evaluating their impact. Additionally, you have not performed stability studies to assure that there has been no impact from the presence of (b) (4). (b) (4) recoveries have included, but have not been limited to, the following:

I. (b) (4), confirmed recovery from near a (b) (4) Flexbumin (b) (4) (b) (4) area, during the manufacturing of lots (b) (4).

II. (b) (4), false positive recovery near (b) (4) Flexbumin manufacturing processes, during the manufacturing of lots (b) (4).

III. (b) (4), confirmed recovery from employee (b) (4) manufacturing process, during the manufacturing of lots (b) (4).

IV. (b) (4) confirmed recovery from (b) (4) Flexbumin manufacturing processes. You were notified by the (b) (4) on January 10, 2025 and issued (b) (4) to continue manufacturing on January 11, 2025.

V. (b) (4), confirmed recovery from (b) (4) Room (b) (4) in Flexbumin manufacturing process. Though you performed investigation (b) (4), this investigator did not adequately address the impact of lot (b) (4).

B. Your firm did not close corrective and preventive actions (CAPA) within established time frames and failed to implement effectiveness checks to prevent recurrence of quality issues. CAPA No. 4909673, initiated on (b) (4), with a target closure date of (b) (4), remains open as of November 4, 2025. This CAPA concerned extrinsic particulate matter identified as (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Peng Zhou, Investigator Shafiq Ahadi, Investigator	X Peng Zhou Investigator Signed By: 2002104595 Date Signed: 11-26-2025 12:30:47	11/26/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	10/27/2025-11/26/2025* FEI NUMBER 3012385969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Hassan M. Zain, Interim Site Head	
FIRM NAME BAXALTA US INC.	STREET ADDRESS 25212 W Il Route 120
CITY, STATE, ZIP CODE, COUNTRY Round Lake, IL 60073-9610	TYPE ESTABLISHMENT INSPECTED Manufacturer

(b) (4) found in Flexbumin lot No. (b) (4) manufactured on November 21, 2023.

C. The inadequacy of the corrective actions for CAPA No. 4909673 is demonstrated by the continued occurrence of the same issue, as evidenced by the opening of CAPA No. 5165429, opened on May 23, 2025, for the same type of particulate matter contamination found in Flexbumin lot No. (b) (4) (b) (4) manufactured on September 4, 2025.

OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A. Flexbumin manufactured at your facility has not been tested for potential (b) (4) cross-contamination. You do not have a validated method to test for (b) (4) in Flexbumin drug product; approximately (b) (4) lots have been manufactured between September 15, 2022 and October 27, 2025, of which (b) (4) lots were for the US market.

B. Surface (b) (4) recovery samples are subject to the current preliminary method by (b) (4) Protocol PD-97-0420-B "Analytical Validation of Procedures for the Detection of (b) (4) in Environmental Samples" and if a positive result is obtained, testing is then performed with a confirmatory test method, Procedure RD-02-01-020 " (b) (4) Limit Test as a Referee Method for Medical Products",. Neither can detect (b) (4) .

C. You have not performed a risk assessment to evaluate the impact of sterility testing performed in a (b) (4) building.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Peng Zhou, Investigator Shafiq Ahadi, Investigator X Peng Zhou Investigator Signed By: 2002104595 Date Signed: 11-26-2025 12:30:47	11/26/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	10/27/2025-11/26/2025* FEI NUMBER 3012385969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hassan M. Zain, Interim Site Head

FIRM NAME	STREET ADDRESS
BAXALTA US INC.	25212 W Il Route 120
CITY, STATE, ZIP CODE, COUNTRY Round Lake, IL 60073-9610	TYPE ESTABLISHMENT INSPECTED Manufacturer

OBSERVATION 4

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

During FLEXBUMIN® 5% Albumin (Human) final drug product inspection, production and process control deviations are not documented at the time of occurrence. The firm's procedure "Evaluation of Particulate Matter (b) (4) Document No. (b) (4), Version 6.0, Section 4.2, effective date October 16, 2025 requires that when particulate matter defects are identified during either the (b) (4) (b) (4) inspection or the (b) (4) inspection, Manufacturing Supervision must be notified to issue and approve a deviation form (FORM(b) (4)) to document and investigate the defects.

For example, particulate matter found during final product inspection of FLEXBUMIN®, lot (b) (4), Expiration date June 2027, on October 30, 2025 was not documented concurrently by technicians in the (b) (4) system. Documentation of the presence of particulates only occurred after management approved the (b) (4) (b) (4).

OBSERVATION 5

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

During the walkthrough on October 29, 2025, (b) (4) and (b) (4) were observed in (b) (4) and (b) (4) of the (b) (4) that supplies (b) (4) for the (b) (4) process in your (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Peng Zhou, Investigator Shafiq Ahadi, Investigator	X Peng Zhou Investigator Signed By: 2002104595 Date Signed: 11-26-2025 12:30:47	11/26/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	10/27/2025-11/26/2025* FEI NUMBER 3012385969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hassan M. Zain, Interim Site Head

FIRM NAME	STREET ADDRESS
BAXALTA US INC.	25212 W Il Route 120
CITY, STATE, ZIP CODE, COUNTRY Round Lake, IL 60073-9610	TYPE ESTABLISHMENT INSPECTED Manufacturer

area, as well as is the (b) (4) source for cleaning of equipment used in the manufacture of Flexbumin. There is no documentation that these maintenance issues have been documented and evaluated.

***DATES OF INSPECTION**

10/27/2025(Mon), 10/28/2025(Tue), 10/29/2025(Wed), 10/30/2025(Thu), 10/31/2025(Fri), 11/03/2025(Mon), 11/04/2025(Tue), 11/05/2025(Wed), 11/06/2025(Thu), 11/07/2025(Fri), 11/10/2025(Mon), 11/12/2025(Wed), 11/13/2025(Thu), 11/14/2025(Fri), 11/26/2025(Wed)

X Shafiq Ahadi
Investigator
Signed By: 2000594974
Date Signed: 11-26-2025 12:31:35

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Peng Zhou, Investigator Shafiq Ahadi, Investigator X Peng Zhou Investigator Signed By: 2002104595 Date Signed: 11-26-2025 12:30:47	11/26/2025

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."