DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483response@fda.hhs.gov	07/13-17/2026
	FEI NUMBER 3002980818

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. Muthyala V.V.S.N. Murthy, Senior General Manager – Operations, Plant Head	
FIRM NAME Wanbury, Limited	STREET ADDRESS K.Illindalaparru (Tanuku), West Godavari Dist.
CITY, STATE, ZIP CODE, COUNTRY Andhra Pradesh, 534217 India	TYPE ESTABLISHMENT INSPECTED Non-sterile API 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

Process validation is deficient in that an unexpected amount of raw material than specified in your validated process was needed in order to produce an active pharmaceutical ingredient.

Specifically,
Deviation 001/23, covering (b) (4) batches (b) (4), reports lower levels of (b) (4) was needed to (b) (4) than required by your validated process.

A) For (b) (4) batch (b) (4), your batch production record specified that no less than (b) (4) of (b) (4) is needed to (b) (4) However, at step number (b) (4) only (b) (4) was needed, for a total of (b) (4) of a minimum of (b) (4) This is approximately (b) (4) (b) (4) less than the validated process requires.

B) For (b) (4) batch (b) (4), your batch production record specified that no less than (b) (4) of (b) (4) is needed to (b) (4) However, at step number

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(b) (4), only (b) (4) was needed, for a total of (b) (4) of a minimum of (b) (4). This is approximately (b) (4) (b) (4) less than the validated process requires.

However, your investigation reported that the root cause is "batch to batch variability" without reasoning why approximately (b) (4), respectively, of the required amount wasn't needed for this process.

OBSERVATION 2

Established procedures are not followed for equipment cleaning, and cleaning records do not accurately reflect actual cleaning activities.

Specifically,

A) On July 13, 2026, during a facility walkthrough of the API manufacturing area, Block (b) significant quantities of visible product residues of (b) (4) were observed on both the external and internal surfaces of (b) (4) Equipment (b) (4) following (b) (4) processing operations for Batch Nos. (b) (4). Despite the presence of these significant residues, the equipment usage and cleaning logbooks reflected that cleaning had been completed, and equipment status labels indicated the equipment was in a "Cleaned" state. Physical inspection of the affected equipment and interviews with the operators confirmed that the required batch-to-batch cleaning procedure, as specified in SOP No. W3/PR(b) (4) /041, had not been performed.

Additionally, (b) (4) had no designated provision in the Batch Production Record (BPR) or any equipment logbook to record cleaning activities. No separate logbook for the (b) (4) was in place, and cleaning of the (b) (4) was not documented.

B) On July 13, 2026, during the manufacture of (b) (4), Batch No.

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(b) (4), the equipment usage and cleaning logs for (b) (4) contained no documentation demonstrating that batch-to-batch cleaning was performed prior to commencement of the subject batch, as required by SOP No. W3/PR(b) (4) /007.
Furthermore, the equipment status labels on (b) (4) reflected the previous batch information rather than the current batch being processed, indicating that the equipment status had not been updated prior to commencement of manufacturing operations for Batch No. (b) (4)

C) On July 13, 2026, during the facility walkthrough of Block(b) (4) the equipment status of (b) (4) (b) (4) changed three times within approximately 60 minutes during the inspection, from no recorded status, to "Cleaned," to "Under Process." Upon observing the "Cleaned" status, the investigator requested that the firm open the (b) (4) to verify cleanliness. As firm personnel were preparing to open the(b) (4), visible fumes were observed emanating from the vessel. When questioned, the operator disclosed that the (b) (4) had already been(b) (4) with approximately (b) (4) of recovered (b) (4) intended for Batch No. (b) (4) and subsequently changed the equipment status to "Under Process."
The (b) (4) contained a significant quantity of solvent at the time the status indicated "Cleaned," and did not reflect the actual condition of the equipment. Status changes were made reactively during the inspection rather than contemporaneously with manufacturing operations.

OBSERVATION 3
A mandatory process step specified in the approved Batch Production Record (BPR) was not performed, and manufacturing activities were not contemporaneously documented.

Specifically,
On July 13, 2026, during the manufacture of (b) (4), Batch No. (b) (4), the mandatory process requirement of (b) (4) (b) (4) (Operation No. (b) (4) per BPR No. (b) (4) was not performed. Following

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completion of (b) (4) to the required (b) (4), the process was advanced directly to (b) (4) operations using equipment (b) (4) without completing the required holding period.
Furthermore, the initiation of (b) (4) activity was not recorded in the relevant BPR at the time of execution, resulting in incomplete and non-contemporaneous documentation of a manufacturing step.

OBSERVATION 4
Adequate records are not maintained to ensure complete accountability and traceability of recovered solvents used in the manufacture of APIs.

Specifically,
During the inspection, the firm operator confirmed that (b) (4) of recovered (b) (4) (b) (4) had been (b) (4) for Batch No. (b) (4) and identified the storage tanks from which the solvent was drawn; however, firm management was unable to reconcile the quantity of recovered (b) (4) transferred from the identified storage tanks against the quantity (b) (4) (b) (4), and could not provide verifiable contemporaneous documentation to support the quantity transferred or demonstrate complete material accountability for the (b) (4) solvent.

Upon further verification of recovered (b) (4) reconciliation records, your firm identified a discrepancy in solvent accountability. A total of (b) (4) of recovered (b) (4) was generated under Batch No. (b) (4). For Batch No. (b) (4) was drawn from Batch No. (b) (4) and an additional (b) (4) was drawn from a separate recovery batch, Batch No. (b) (4), together totaling (b) (4) consumed. Accordingly, an expected balance of (b) (4) from Batch No. (b) (4) should have remained available in storage tanks (b) (4) Physical verification of these tanks revealed only (b) (4) present, representing an apparent shortfall of (b) (4) that could not be reconciled at the time of inspection.

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OBSERVATION 5
Laboratory records are not accurate and/or complete, and are not reviewed by a second person.

Specifically,
A) Growth Promotion Test (GPT) results for (b) (4) batch (b) (4) were not recorded, and the analytical data sheet was not completed prior to media release; nevertheless, this media was released and used for finished product microbiological testing.

B) Growth Promotion Test (GPT) results for (b) (4) batch (b) (4) were recorded as colony counts despite the fact that GPT was performed using a (b) (4) medium, in which colony enumeration is scientifically impossible; these erroneous results were signed by both the analyst and the reviewer, and the media was subsequently used for microbiological testing of multiple API batches.

C) Additionally, during the inspection on 13th July 2026, the microbiology reviewer had not signed the analytical records contemporaneously for (b) (4) water testing, and the microbiological test plates were (b) (4) and destroyed prior to review and sign-off by the reviewer.

OBSERVATION 6
Inadequate Microbiological Risk Management and Non-Conformance Investigation Procedures.

Specifically
A) Your firm has not conducted a documented risk-based impact assessment to evaluate the microbiological risks associated with (b) (4) water system, including a failure to evaluate the need for *Burkholderia cepacia* complex testing.

B) Your firm's non-conformance investigation procedures for both (b) (4) water microbiological

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testing (SOP W3/QC/MB/GEN/015) and finished product microbiological testing (SOP W3/QC/MB/FP/003) do not require organism identification following an excursion at the alert limit, action limit, or out-of-specification stage.

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