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	06/22-30/2026
	FEI NUMBER 3004672766

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ganpat Sonyabapu Pote, Vice President Operation & Site Head	
FIRM NAME Glenmark Pharmaceuticals Limited	STREET ADDRESS Plot No. S-7, Colvale Industrial Estate,
CITY, STATE, ZIP CODE, COUNTRY Colvale, Bardez, Goa 403 513, India	TYPE ESTABLISHMENT INSPECTED Drug 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

Equipment and utensils are not cleaned or sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. Inadequate Cleaning Procedures - Insufficient Time Allocation
Your firm's written cleaning procedure, SOP CM/PD002 "Cleaning and Sanitization of Production Areas, Other than Production Areas, Wash Areas and Drain Points", establishes requirements for Type A cleaning and Type B cleaning of (b) (4) manufacturing rooms. Type A cleaning is performed during continued production of the same product, while Type B cleaning is performed during product changeover to prevent cross-contamination between different drug products

Review of cleaning records for (b) (4) rooms revealed documented cleaning times that are physically insufficient to complete all required procedural steps.

1. Type A Cleaning – Examples of Inadequate Times
Type A cleaning requires sequential steps for (b) (4) operations

JARED P. STEVENS -S Digitally signed by JARED P. STEVENS -S Date: 2026.06.30 16:06:46 +05'30'

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator Jared P. Stevens, Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2026.06.30 16:10:35 +05'30' RAFEEQ HABEEB -S Digitally signed by RAFEEQ HABEEB -S Date: 2026.06.30 16:03:09 +05'30'	06/30/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483response@fda.hhs.gov	06/22-30/2026
	FEI NUMBER 3004672766
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ganpat Sonyabapu Pote, Vice President Operation & Site Head	
FIRM NAME Glenmark Pharmaceuticals Limited	STREET ADDRESS Plot No. S-7, Colvale Industrial Estate,
CITY, STATE, ZIP CODE, COUNTRY Colvale, Bardez, Goa 403 513, India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

(b) (4) The following examples demonstrate that documented cleaning times do not allow completion of all required steps:

- March 17, 2026: (b) (4) Room (b) (4) (1 minute) – documented as completing (b) (4)
- August 18, 2025: (b) (4) Room (b) (4) (5 minutes) – documented as completing (b) (4)
- March 18, 2026: (b) (4) Room (b) (4) (5 minutes) – documented as completing (b) (4)

2. Type B Cleaning – Examples of Inadequate Times
Type B cleaning is performed during product changeover and requires more extensive cleaning than Type A, including wet cleaning (using (b) (4) (b) (4) and visual inspection of cleaned areas to confirm effectiveness. Review of Type B cleaning records revealed that documented times are insufficient to complete all required steps:

- April 22, 2026: (b) (4) (Unit (b) (4) , Room (b) (4) (14 minutes) – documented as completing wet cleaning of (b) (4) (b) (4) operations, and visual inspection of floor corners, edges, and under-equipment areas
- January 16, 2025: (b) (4) Facility (Unit (b) (4) Room (b) (4) (b) (4) (8 minutes) – documented as completing wet cleaning of (b) (4) (b) (4)

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator Jared P. Stevens, Investigator	RAH LLF JPS	06/30/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483response@fda.hhs.gov	06/22-30/2026
	FEI NUMBER 3004672766
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ganpat Sonyabapu Pote, Vice President Operation & Site Head	
FIRM NAME Glenmark Pharmaceuticals Limited	STREET ADDRESS Plot No. S-7, Colvale Industrial Estate,
CITY, STATE, ZIP CODE, COUNTRY Colvale, Bardez, Goa 403 513, India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

- (b) (4) operations, and required visual inspection.
- February 13, 2025: (b) (4) Facility (Unit (b) (4) Room (b) (4) (b) (4) (5 minutes) – documented as completing wet cleaning of (b) (4) and required visual inspection.
- February 21, 2025: (b) (4) (Unit (b) (4) Room (b) (4) (b) (4) (11 minutes) – documented as completing wet cleaning of (b) (4) operations, and required visual inspection.

Your firm has not established a minimum or validated cleaning time for Type A and Type B cubicle cleaning. Without scientifically justified time requirements, there is no basis to determine whether documented cleaning times are adequate to complete all required procedural steps.

B. Lack of Validated Contact Time for Disinfectants

1. Protocol MSP/QC/2023/005/00/CMPD002 (effective 13/02/2023) and Summary Report MSR/QC/2023/005/00/CMPD002 (dated 01/06/2024) were conducted to demonstrate the effectiveness of the disinfectants used in the sanitization procedure. However, the study design cannot demonstrate disinfectant efficacy because it lacks the following critical elements:
   - Positive controls
   - Pre-cleaning microbial counts

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator Jared P. Stevens, Investigator	LLF RAH JPS	06/30/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483response@fda.hhs.gov	06/22-30/2026
	FEI NUMBER 3004672766
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ganpat Sonyabapu Pote, Vice President Operation & Site Head	
FIRM NAME Glenmark Pharmaceuticals Limited	STREET ADDRESS Plot No. S-7, Colvale Industrial Estate,
CITY, STATE, ZIP CODE, COUNTRY Colvale, Bardez, Goa 403 513, India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

- Deliberate microbial challenge
- Untreated control surfaces
- Inadequate Acceptance Criteria

2. The study's acceptance criteria of "Total aerobic Microbial count: NMT (b) (4) cfu/plate" fails to demonstrate disinfectant efficacy for two reasons:
   - The acceptance criteria is identical to routine environmental monitoring limits for Grade D areas and therefore does not demonstrate disinfectant efficacy. The acceptance criteria measures surface cleanliness, meaning there is no scientific basis to distinguish between effective disinfection and low baseline contamination.
   - There is no scientific justification for the absence of a log reduction calculation requirement. Your firm's own 2016 validation (Protocol VP/MM/QC/206) established acceptance criteria of ≥(b) (4) %) reduction for vegetative organisms and ≥(b) (4) (b) (4) %) reduction for spores, yet these standards were not applied in Protocol MSP/QC/2023/005/00/CMPD002 (effective 13/02/2023) and Summary Report MSR/QC/2023/005/00/CMPD002 (dated 01/06/2024).

C. Absence of Validated Contact Time

Your firm has not established or validated a minimum contact time for any of the (b) (4) disinfectants used (b) (4) The absence of specified contact times, combined with the inadequate total cleaning times documented above, could indicate that effective sanitization is not being achieved. In the documented cleaning records, if all procedural steps are completed within the allocated time, there is no remaining time for disinfectant to remain in contact with floor surfaces before the room is returned to use.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483response@fda.hhs.gov	06/22-30/2026
	FEI NUMBER 3004672766
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ganpat Sonyabapu Pote, Vice President Operation & Site Head	
FIRM NAME Glenmark Pharmaceuticals Limited	STREET ADDRESS Plot No. S-7, Colvale Industrial Estate,
CITY, STATE, ZIP CODE, COUNTRY Colvale, Bardez, Goa 403 513, India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

OBSERVATION 2

Appropriate controls were not exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

A. (b) (4) machines—the (b) (4) (b) (4) are all documented as having no electronic data storage or audit trail capability. These machines are used to manufacture multiple tablet products for distribution in the United States, including (b) (4) (b) (4) As a result:

1. The (b) (4) machines lack electronic data storage and audit trail functionality. While printed reports are generated and subsequently scanned for archival, the original electronic data on the machines themselves cannot be retrieved, trended, or audited. This prevents verification of:
    a. Authorization status of changes at the time they were made
    b. Detection of unauthorized modifications to data other than process parameters
    c. Systematic trending of parameter drift or equipment performance degradation
2. There is no documented procedure establishing acceptable limits on the number or magnitude of parameter adjustments an operator may make during a single batch run within the validated range. An operator may make unlimited corrections to (b) (4) or other parameters without documented justification, and there is no mechanism to detect whether such frequent adjustments indicate process instability or equipment drift.
3. While non-critical alarms are logged in batch records and a Work Request Memo (WRM) system exists to document equipment issues requiring engineering intervention, there is no documented procedure establishing threshold criteria (frequency or severity triggers) that

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator Jared P. Stevens, Investigator	LLF RAH JPS	06/30/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483response@fda.hhs.gov	06/22-30/2026
	FEI NUMBER 3004672766
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ganpat Sonyabapu Pote, Vice President Operation & Site Head	
FIRM NAME Glenmark Pharmaceuticals Limited	STREET ADDRESS Plot No. S-7, Colvale Industrial Estate,
CITY, STATE, ZIP CODE, COUNTRY Colvale, Bardez, Goa 403 513, India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

define when non-critical alarms require investigation and escalation beyond routine maintenance.

B. (b) (4) machines—the (b) (4) —are used to manufacture multiple tablet products for distribution in the United States, including (b) (4) Although these machines are equipped with electronic data storage and backup capability, appropriate controls are not exercised to assure that changes to process parameters are instituted only by authorized personnel, and procedures do not establish monitoring and investigation requirements for equipment "Non-Critical" alarms and parameter deviations.

Specifically:

1. While the electronic audit trail captures date, time, personnel identity, old value, and new value of parameter changes, your procedures do not establish requirements to review the audit trail for: the sequence and frequency of parameter changes during a batch, whether changes were made for documented reasons, whether the pattern of changes indicates process instability or equipment drift, or whether changes were appropriate given the product and process stage. The audit trail is reviewed only for compliance with specification limits, not for assessment of the adequacy or appropriateness of the changes themselves.
2. Your procedures do not establish requirements to monitor the frequency or pattern of non-critical alarms, define investigation criteria or trigger points for repeated non-critical alarms that may indicate emerging equipment problems, or require documentation of non-critical alarm occurrences for trend analysis.
3. While your SOPs establish acceptance limits for process parameters and define alarm thresholds, the procedures do not establish predefined investigation criteria for parameter deviations that do not generate alarms. The SOPs do not establish predefined trigger points

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator Jared P. Stevens, Investigator	LLF RAH JPS	06/30/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483response@fda.hhs.gov	06/22-30/2026
	FEI NUMBER 3004672766
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ganpat Sonyabapu Pote, Vice President Operation & Site Head	
FIRM NAME Glenmark Pharmaceuticals Limited	STREET ADDRESS Plot No. S-7, Colvale Industrial Estate,
CITY, STATE, ZIP CODE, COUNTRY Colvale, Bardez, Goa 403 513, India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

for investigation of parameter drift within acceptable limits or trend monitoring of parameters that remain within specification but show directional drift.

OBSERVATION 3

Each component is not tested for conformity with all written specifications for purity, strength, and quality.

Specifically,

Your firm failed to perform individual container testing, including identity testing with limits for (b) (4) (NMT (b) (4) %), on each individual container of each shipment of each lot of high-risk drug components prior to their use in manufacturing of drug products distributed to the United States market. Your procedure for sample testing, Sampling, Testing and Release of Raw Materials, SOP 19/QC006, allows analysis of (b) (4) samples.

The high-risk raw materials tested using (b) (4) samples include:

Raw Material	Most recent Glenmark material batch #
(b) (4)	

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483response@fda.hhs.gov	06/22-30/2026
	FEI NUMBER 3004672766
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ganpat Sonyabapu Pote, Vice President Operation & Site Head	
FIRM NAME Glenmark Pharmaceuticals Limited	STREET ADDRESS Plot No. S-7, Colvale Industrial Estate,
CITY, STATE, ZIP CODE, COUNTRY Colvale, Bardez, Goa 403 513, India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

(b) (4)

These raw materials have been used to manufacture commercial product intended for the US market including (b) (4)

OBSERVATION 4

Control systems for the firm's operations are not adequate to prevent contamination or mix-ups.

Specifically,

A. Differential pressure in the manufacturing areas of the (b) (4) facility (Unit (b) is not adequately monitored and recorded, and no alarm system is in place to detect differential pressure excursions. A review of the Batch Production Record (BPR) for Batch (b) (4) (b) (4) USP (b) mcg), confirmed that the differential pressure is recorded only during active batch production, approximately (b) (4) with no continuous monitoring or alarm system to ensure pressure differentials are maintained. Your firm manufactures (b) (4) drug products approved for the U.S. market in Unit (b) (4) Approximately (b) (4) distinct batches—including (b) (4)

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator Jared P. Stevens, Investigator	LLF RAH JPS	06/30/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483response@fda.hhs.gov	06/22-30/2026
	FEI NUMBER 3004672766
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ganpat Sonyabapu Pote, Vice President Operation & Site Head	
FIRM NAME Glenmark Pharmaceuticals Limited	STREET ADDRESS Plot No. S-7, Colvale Industrial Estate,
CITY, STATE, ZIP CODE, COUNTRY Colvale, Bardez, Goa 403 513, India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

(b) (4) —were shipped to the U.S. between January 2023 and June 2026. Your firm also manufactures (b) (4) (b) (4) tablets in the same facility as (b) (4) products and these (b) (4) tablets are (b) (4) packaged with (b) (4) tablets for at least (b) (4) commercial products marketed in the U.S. All these approximately (b) (4) batches remain within their approved expiry dates as of the date of this inspection (June 30, 2026).

B. Although a risk assessment with containment study was done in 2023 and 2025, your firm has not conducted a comprehensive risk assessment prior to this inspection on June 22, 2026, to evaluate the potential for cross-contamination between the (b) (4) manufacturing facility (Unit (b) (4) and the (b) (4) facility (Unit (b) (4) The Units are located approximately (b) (4) away from each other. For example, your firm has not performed a scientific evaluation of potential (b) (4) cross-contamination between the two facilities, including an assessment of the location and (b) (4) points of the (b) (4) facility's (b) (4) systems in relation to the (b) (4) vents of the (b) (4) facility; the adequacy and a program for periodic environmental monitoring between the facilities.

OBSERVATION 5

Written procedures for annual product reviews are not followed, and the reviews are deficient in that they do not address a review of complaint records for each drug product.

Specifically,

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator Jared P. Stevens, Investigator	LLF RAH JPS	06/30/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483response@fda.hhs.gov	06/22-30/2026
	FEI NUMBER 3004672766
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Ganpat Sonyabapu Pote, Vice President Operation & Site Head	
FIRM NAME Glenmark Pharmaceuticals Limited	STREET ADDRESS Plot No. S-7, Colvale Industrial Estate,
CITY, STATE, ZIP CODE, COUNTRY Colvale, Bardez, Goa 403 513, India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

Your firm failed to include a review of all complaints in the Annual Product Quality Review (APQR). Your procedure, "SOP CM/QA005, Revision 17: Periodic Review of Product Quality of Drug Products," requires the compilation of market complaints for the APQR. However, complaints were not included in the APQR for the following products

A. Product: (b) (4) Tablets

The APQR for the review period of March 25, 2024, to March 24, 2025 (APQR/25/US/007) reported zero (0) market complaints. However, a review of your firm's complaint records identified eleven (11) complaints associated with this product within the review period that were not included in the APQR including complaints for lack of efficacy and missing blisters.

B. Product: (b) (4) Tablets

The APQR for the review period of January 19, 2024, to January 18, 2025 (APQR/25/US/001) reported one (1) market complaint. However, a review of your firm's complaint records identified a total of two (2) complaints associated with this product within the review period. Complaint number MC/I102/2024/0065 for missing blister was not included in the APQR.

OBSERVATION 6

Laboratory records do not include complete data derived from all tests, examinations, and assays necessary to assure compliance with established specifications and standards.

Specifically,

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator Jared P. Stevens, Investigator	LLF RAH JPS	06/30/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483response@fda.hhs.gov	06/22-30/2026
	FEI NUMBER 3004672766

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ganpat Sonyabapu Pote, Vice President Operation & Site Head	
FIRM NAME Glenmark Pharmaceuticals Limited	STREET ADDRESS Plot No. S-7, Colvale Industrial Estate,
CITY, STATE, ZIP CODE, COUNTRY Colvale, Bardez, Goa 403 513, India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

Your analysts have been granted user privileges within the Empower software that allow them to view numerical results in the review window—including area counts of peaks—while changing processing methods, without requiring the chromatograms to be saved. This configuration allows for the potential previewing of data. While these series of controls were in place, your firm has tested over (b) (4) batches of finished drug products for assay and/or impurities by HPLC since January 2023. These products include, but are not limited to, (b) (4)

(b) (4)

Furthermore, prior to this inspection, your firm did not conduct a comprehensive risk assessment to identify and control the data integrity risks introduced by these user privilege configurations.

JARED P. STEVENS -S
Digitally signed by JARED P. STEVENS -S
Date: 2026.06.30 16:07:13 +05'30'

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator Rafeeq A. Habeeb, Investigator Jared P. Stevens, Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2026.06.30 16:11:07 +05'30' RAFEEQ HABEEB -S Digitally signed by RAFEEQ HABEEB -S Date: 2026.06.30 16:03:54 +05'30'	06/30/2026