DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	5/11/2026-5/18/2026* FEI NUMBER 3017140477

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Shailesh (nmi) Vengurlekar, Senior V.P - Quality & Regulatory Affairs

FIRM NAME	STREET ADDRESS
LGM Pharma Solutions, LLC	17802 Gillette Ave
CITY, STATE, ZIP CODE, COUNTRY Irvine, CA 92614-6502	TYPE ESTABLISHMENT INSPECTED Drug Product Manufacturer and 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:

PRODUCTION SYSTEM

OBSERVATION 1

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,

Your firm failed to establish adequate controls to manage variability in commercial production of (b) (4) Tablets despite acknowledging in both the Validation Protocol (DOC-021270) and Validation Report (DOC-021423) that (b) (4) is a naturally variable material with inherent physical and chemical variability. For example:

1. Multiple Out-of-Specification (OOS) investigations were initiated following above-specification results. Three of these OOS results (CA25-018, CA25-048, and CA25-063) were linked to Batch (b) (4), which also showed an (b) (4) assay trend, while one additional OOS result (CA25-019) was associated with Batch (b) (4). Both batches had been released in December 2024 and are currently on stability studies.
2. The batch record lists hardness and thickness limits as "Record Only," providing no enforceable in-process trigger to detect or respond to compression drift during tableting.

LABORATORY SYSTEM

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Thuy Tram L Nguyen, Investigator Journey V Cordero, Investigator Walden H Lee, Chemist/Biologist Jay-Ar C Bendo, Chemist/Biologist Devisree P Mattigiri, Investigator X Devisree P Mattigiri Investigator Signed By: DEVISREE P. MATTIGIRI -S Date Signed: 05-18-2026 13:52:07	5/18/2026

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OBSERVATION 2

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

Specifically,

1. Your specifications for assay of (b) (4) tablet, a (b) (4) drug, does not appear to be sufficiently (b) (4) as the specifications are set at (b) (4)

2. The Assay Method Validation Report for (b) (4) (b) (4) is incomplete and has not been updated in accordance with current procedures. For example:

a) The validation report covers only Accuracy, Precision, Linearity, LOD/LOQ, Ruggedness, and Robustness; Specificity, (b) (4) Study, and Solution Stability parameters are absent from the report.

b) The validation was conducted in 2007, predating the implementation of DOC-015071 "General Guidelines for Method Validation/Verification" (effective 2023) by approximately 16 years, and the report has not been revised to reflect current validation requirements outlined therein.

QUALITY SYSTEM

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

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Your firm failed to thoroughly investigate three recurring Total Aerobic Microbial Count (TAMC) Negative Control OOS failures (OOS CA25-050, CA25-052, and CA25-057) occurring between August 19 and September 19, 2025. Each failure was treated as an isolated incident attributed to analyst error, without evaluating the (b) (4) (Lot # (b) (4) , Bottle # (b) (4)), which was a common material shared across all three events, as a potential root cause, and without extending the investigation to other potentially affected batches and products. Lot # (b) (4) was used to test (b) (4) different samples prior to disposal. The true root cause, a pre-contaminated (b) (4) bottle, was not identified until the third OOS event (CA25-057), when visible microbial growth was observed in the remaining (b) (4).

OBSERVATION 4

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically,

Your firm's annual product review process includes visual examination of a subset lots of reserve samples during the first year, according to SOP titled "Annual Product Review" (DOC-001071, Rev 10, Effective Date 14 March 2023). Your firm has not conducted the required annual visual examinations of reserve samples in subsequent years to assess for signs of deterioration. For example, for the 2022–2023 review period, retain samples for all (b) (4) manufactured lots of (b) (4) (b) (4) Capsule were examined in August 2023 but were not re-examined in 2024, despite the products remaining within their expiry dates.

***DATES OF INSPECTION**

5/11/2026(Mon), 5/12/2026(Tue), 5/13/2026(Wed), 5/14/2026(Thu), 5/15/2026(Fri), 5/18/2026(Mon)

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X Jay-Ar C Bendo
Chemist/Biologist
Signed By: JAY-AR C. BENDO -S
Date Signed: 05-18-2026 13:52:51

X Walden H Lee
Chemist/Biologist
Signed By: 1300071161
Date Signed: 05-18-2026 13:53:30

X Journey V Cordero
Investigator
Signed By: JOURNEY V. CORDERO -S
Date Signed: 05-18-2026 13:54:16

X Thuy Tram L Nguyen
Investigator
Signed By: Thuy Tram Nguyen -S
Date Signed: 05-18-2026 13:54:50

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EMPLOYEE(S) SIGNATURE

Thuy Tram L Nguyen, Investigator
Journey V Cordero, Investigator
Walden H Lee, Chemist/Biologist
Jay-Ar C Bendo, Chemist/Biologist
Devisree P Mattigiri, Investigator

X Devisree P Mattigiri
Investigator
Signed By: DEVISREE P. MATTIGIRI -S
Date Signed: 05-18-2026 13:52:07

DATE ISSUED
5/18/2026

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."