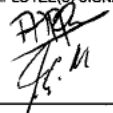


DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION 02/04/2026-02/09/2026	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Vasanth Samaga, Founder-Director		FEI NUMBER 3013697420	
FIRM NAME Biomylyz Private Limited	STREET ADDRESS #21 BUILDING NO 1		
CITY, STATE, ZIP CODE, COUNTRY Bengaluru, 560058, India	TYPE ESTABLISHMENT INSPECTED OTC 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			
Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed.			
On January 22, 2026, your firm terminated the former Plant Manager due to repeated and ongoing data integrity violations, including, but not limited to, destruction of batch production records, destruction of laboratory-controlled records, and documentation of false production and laboratory data. According to your Quality Head, employees working in the production and laboratory areas were instructed by the former Plant Manager to destroy, alter, or manipulate records and felt compelled to comply due to his supervisory authority. This inadequate practice was also observed and confirmed by your Operations Manager to whom the former Plant Manager reported to.			
Despite these identified data integrity concerns, your firm did not initiate an investigation or conduct a comprehensive evaluation of manufacturing and laboratory records associated with OTC drug products manufactured for the U.S. market to determine the extent and impact of the data integrity breaches.			
In addition, your firm did not perform reconciliation of incoming raw materials, finished drug products manufactured and released, inventory records, equipment usage logbooks, laboratory test results, sample			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Alan A. Rivera, Investigator Jose E. Melendez, DDC Investigator	DATE ISSUED February 9, 2026
FORM FDA 483 (09/08)		PREVIOUS EDITION OBSOLETE	
INSPECTIONAL OBSERVATIONS			
Page 1 OF 6			

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION 02/04/2026-02/09/2026	
		FEI NUMBER 3013697420	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Vasanth Samaga, Founder-Director			
FIRM NAME Biomylz Private Limited		STREET ADDRESS #21 BUILDING NO 1	
CITY, STATE, ZIP CODE, COUNTRY Bengaluru, 560058, India		TYPE ESTABLISHMENT INSPECTED OTC Drug Manufacturer	
collection records, or batch production records to determine whether additional discrepancies or undocumented activities occurred. In addition, your firm did not implement interim controls to prevent recurrence of data integrity failures. The former Plant Manager oversaw production operations from June 2019 through January 2026. Since March 2024, your firm has manufactured (b) (4) lots of (b) (4) (b) (4) intended for the U.S. market, all of which remain within their expiration dates. Moreover, on February 4, 2026, during the initial inspectional walkthrough of your facility, the following data integrity deficiencies were observed: A. Destroyed controlled records containing raw data were observed inside a trash bag located in the scrap room. The recovered documents included, but were not limited to, executed production batch records; media preparation, incubation, and sterilization cycle logbook pages; finished product sample collection forms; environmental monitoring sample forms; and change control log forms. B. The Incubation Usage Log, Book Number (b) (4) Reference SOP: QCD-M/007 & III, contained (b) (4) (b) (4) entries (Serial Numbers (b) (4) through (b) (4) that were signed by the analyst (QC Microbiologist) and verified by a second person (QC Chemist) despite incubation end date not being reported. C. Controlled documents issued by Quality Assurance were not adequately controlled or reconciled. Specifically, your firm did not perform document retrieval as required by logbook (Book Number: (b) (4) titled "Formats/Document Issuance & Retrieval Log", Reference SOP: QAD/004 II, to ensure that all controlled printed copies were returned to Quality Assurance and reconciled. D. The Media Preparation Sterilization and Weight Balance Log, Book Number (b) (4) Reference SOP: QCD-M/001 & I), contained (b) (4) media volume entries recorded in pencil rather than permanent ink. According to the analyst, entries were initially recorded in pencil and later overwritten in ink after completion of weight checks. These entries were signed (QC			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Alan A. Rivera, Investigator Jose E. Melendez, DDC Investigator	DATE ISSUED February 9, 2026

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

12420 Parklawn Drive, Room 2032 Rockville, MD 20857

DATE(S) OF INSPECTION

02/04/2026-02/09/2026

FEI NUMBER

3013697420

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Vasanth Samaga, Founder-Director

FIRM NAME

Biomylz Private Limited

STREET ADDRESS

#21 BUILDING NO 1

CITY, STATE, ZIP CODE, COUNTRY

Bengaluru, 560058, India

TYPE ESTABLISHMENT INSPECTED

OTC Drug Manufacturer

Microbiologist) and verified by a second person (QC Chemist) despite media weight not being reported and media volume documented in pencil.

- E. Laboratory logbooks used to document media preparation, pH meter equipment usage, incubator usage, sterilization (b) (4) activities, conductivity meter calibration, and pH meter calibration were observed with pages that were not numbered in advance. As a result, there is no assurance that pages cannot be removed, replaced, or altered without detection, and that laboratory records are complete and reliable.

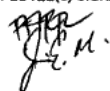
OBSERVATION 2

There are no written procedures for production and process controls designed to assure that the OTC products have the identity, strength, quality and purity they purport or are represented to possess.

- A. For example, your firm has not performed the process validation for (b) (4) OTC product. Nevertheless, your firm has been releasing (b) (4) commercial batches (i.e., (b) (4) Exp Date (b) (4) respectively to be distributed in the USA market.
- B. Your firm has not established stability studies for (b) (4) OTC products distributed to the U.S. market. Specifically, firm management assigned a (b) (4) expiration date for (b) (4) OTC products. However, your firm lacks supporting stability data or other scientifically sound evidence to demonstrate that these products will meet established quality attributes throughout their shelf life.

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

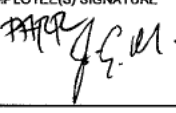


EMPLOYEE(S) NAME AND TITLE (Print or Type)

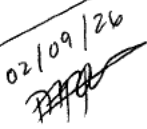
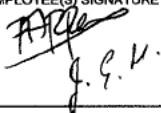
Alan A. Rivera, Investigator
Jose E. Melendez, DDC Investigator

DATE ISSUED

February 9, 2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION 02/04/2026-02/09/2026	
		FEI NUMBER 3013697420	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Vasanth Samaga, Founder-Director			
FIRM NAME Biomylyz Private Limited		STREET ADDRESS #21 BUILDING NO 1	
CITY, STATE, ZIP CODE, COUNTRY Bengaluru, 560058, India		TYPE ESTABLISHMENT INSPECTED OTC Drug Manufacturer	
OBSERVATION 3 Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards. Your firm failed to maintain complete laboratory records, including raw data, for laboratory analyses conducted on commercial drug products. Specifically, raw data supporting laboratory test results used to release commercial batches, to validate the commercial manufacturing process, and/or in house (b) (4) system were not retained or were unavailable for review. OBSERVATION 4 The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically, A. There is no assurance that laboratory testing used to determine raw material suitability and finished drug product quality is performed in accordance with applicable cGMP requirements. For example, your firm uses contracted laboratories that are not registered or inspected by the agency to perform incoming raw material and finished OTC drug product testing, including the Certificate of Analysis (CoA) used to support the release decision. In addition, no Quality Agreements have been established between your firm and the contracted laboratories to define roles, responsibilities, and oversight related to testing, data integrity, and compliance with cGMP requirements. Moreover, no documented evidence was provided, which demonstrates that the selected contracted laboratories have been inspected by your Quality Unit to assess their compliance with applicable cGMP requirements.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Alan A. Rivera, Investigator Jose E. Melendez, DDC Investigator	DATE ISSUED February 9, 2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION 02/04/2026-02/09/2026	
		FEI NUMBER 3013697420	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Vasanth Samaga, Founder-Director			
FIRM NAME Biomytz Private Limited		STREET ADDRESS #21 BUILDING NO 1	
CITY, STATE, ZIP CODE, COUNTRY Bengaluru, 560058, India		TYPE ESTABLISHMENT INSPECTED OTC Drug Manufacturer	
B. A quality agreement has not been established between your firm and the owner of the U.S.-marketed (b) (4) OTC product. As a result, there is no assurance that effective quality systems and controls are consistently implemented, as the roles and responsibilities of each party involved in contract manufacturing, packaging, testing, release, and post-distribution quality activities are not clearly defined. These deficiencies may adversely affect your firm's ability to adequately oversee cGMP activities and to promptly identify, investigate, and address potential quality issues affecting products distributed to the U.S. market. C. Your firm was unable to provide the corrective and preventive action (CAPA) reports generated by your Quality Unit in response to the seventeen (17) objectionable conditions documented in the FDA Form 483 issued during the previous inspection on July 2, 2020.			
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, your firm failed to develop and approve cleaning procedures describing in sufficient detail the methods, equipment and materials to be used for cleaning the production equipment (i.e., (b) (4) tank, holding tank and filling line) and utensils or auxiliary equipment (e.g., transfer lines and filling hoses) used in the manufacture of your (b) (4) OTC product. As per your Quality Manager, your cleaning procedures are executed (b) (4)			
OBSERVATION 6 Your firm failed to maintain buildings used in the manufacture, processing, packing, or holding of drug products in a good state of repair.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Alan A. Rivera, Investigator Jose E. Melendez, DDC Investigator	DATE ISSUED February 9, 2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION 02/04/2026-02/09/2026	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Vasanth Samaga, Founder-Director		FEI NUMBER 3013697420	
FIRM NAME Biomylyz Private Limited		STREET ADDRESS #21 BUILDING NO 1	
CITY, STATE, ZIP CODE, COUNTRY Bengaluru, 560058, India		TYPE ESTABLISHMENT INSPECTED OTC Drug Manufacturer	
On February 4, 2026, during the initial inspectional walkthrough of your facility, we observed that the (b) (4) of your (b) (4) system was leaking from the bottom and at the (b) (4) valve piping connection. Your firm did not perform any corrective actions to repair the (b) (4) at the time of the inspection. (b) (4) by this system is used as a raw material in the formulation of (b) (4) OTC product. In addition, (b) (4) is used as a cleaning agent for equipment and utensils that come into direct contact with the OTC finished product during manufacturing operations. OBSERVATION 7 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, according to your procedure titled "Procedure for Collection and Storage of Control Sample", SOP Number: QCD/009, Version: R04, Effective Date: April 07, 2025, Section 5.1.1 states, "The control sample shall be collected from each batch of finished goods manufactured and from each batch of raw material ingredient received". However, no examination is performed at least once a year to determine if product deterioration in U.S. marketed OTC products that include (b) (4) has occurred. 			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Alan A. Rivera, Investigator Jose E. Melendez, DDC Investigator	DATE ISSUED February 9, 2026