

TMDA/DMD/MCIE/F/002
REV #. 01



THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

MYLAN LABORATORIES LIMITED, NASHIK-INDIA
PUBLIC GMP DESK ASSESSMENT REPORT

MARCH, 2025



**TMDA PUBLIC GMP DESK ASSESSMENT
REPORT**



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Part 1: General information about the company

1.1 Manufacturer's details	
Name of Applicant	Mylan Laboratories Limited, Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad, 500096-Telangana, India Telephone: +91 8458662131
1.2 Inspected site Details	
Name & physical address of inspected manufacturing site	Mylan Laboratories Limited, F-4 & F-12, Malegaon MIDC, Sinnar, Nashik - 422113, Maharashtra, India
Name of Unit/ block/ workshop number inspected	FDF-1
1.3 Inspection details	
Date of desk review	2 nd August, 2024
Date of last inspection by the SRA, WHO-PQ or EAC / SADC for production line applied at TMDA	1 st December, 2023
1.4 Brief report of the activities undertaken at the site	
Summary of the activities performed at the site	Manufacturing and packaging of drug products / medicinal products, testing of the starting materials, in-process materials and finished goods.
Production lines applied at TMDA	General oral solid dosage in the form of tablets and capsules

Part 2: Review of submitted documentary evidence

2.1. Site master file

The Site Master file number SMF/MILLFDF-1/05 effective from 12th October, 2023 was submitted. The SMF was prepared as per requirements stipulated in the TMDA (Good Manufacturing Practice Enforcement) Regulations GN 295.



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2.2. List of all regulatory inspections carried out in the past three years.

The facility was inspected by:

- a. Food and Drugs Administration (Maharashtra State) following inspection on 27/05/2021 – 28/05/2021 and 22/06/2021 and the certificate issued was valid up to 02nd July 2024.
- b. Health Products Regulatory Authority (HPRA) of Ireland following an inspection conducted on 1st December 2023 and the certificate was issued on 27th February, 2024

2.3. Manufacturing license and GMP permit granted by the local National Medicines Regulatory Authority (NMRA).

A valid manufacturing license issued by NRA, i.e. Food and Drugs Administration (Maharashtra State) dated 13th May 2020, was provided. The validity period was from 04/08/2020 to 03/08/2025. Also, a then valid GMP certificate issued by the Food and Drugs Administration (Maharashtra State) following inspection on 27/05/2021 – 28/05/2021 and 22/06/2021 was provided and the certificate issued was valid up to 02nd July 2024

2.4. Valid GMP certificate issued by stringent medicines regulatory authority and/or that from WHO prequalification and Regional Harmonization Initiatives (whichever is applicable) for inspection carried out within the past three years for production line(s) applied at TMDA.

2.4.1. Name of SRAWHO-PQ/RECs

The SRA that inspected the facility was the Health Products Regulatory Authority (HPRA) of Ireland

2.4.2. Dates of inspection 27th November to 1st December, 2023

2.4.3. Scope of GMP certificates/ List of compliant production line

The inspected and compliant production lines were general formulations in form of capsules and tablets



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- 2.4.4. A confirmation by the senior QA representative that a full SRA audit covering the product(s) has been performed and all matters dealt with and attest to the authenticity of the information

Two response letters from Mylan Laboratories Limited to Health Products Regulatory Authority (HPRA), Ireland following an inspection conducted from 27th Nov to 1st Dec 2023 were submitted. Subsequently, the applicant submitted a copy of the Eudra GMP certificate with certificate No. 34168 issued on 27/02/2024 which confirmed a full *SRA audit* covering the product(s) has been performed. Furthermore, the applicant declared in the application form that all the information provided was correct. In this regard, this can be accepted as confirmation and attest to the authenticity of the information.

- 2.5. Regulatory Actions against the facility that were taken in the past three (3) years.

The applicant had submitted two letters dated 12/06/2024 confirming no complaints alerts, warning letters or product recalls were reported for the last three years. Also, the TMDA Substandard and Falsified Register was reviewed and it was observed that there were no such complaints on products manufactured from this facility.

- 2.6. Market complaints in the last three years for products applied at TMDA

The applicant had submitted two letters dated 12/06/2024 confirming no complaints alerts, warning letters or product recalls were reported for the last three years. Also, the TMDA Substandard and Falsified Register was reviewed and it was observed that there were no such complaints on products manufactured from this facility.

Part 3: Conclusion

Based on the desk assessment and evidence(s) provided **Mylan Laboratories Limited, F-4 & F-12, Malegaon MIDC, Sinnar, Nashik - 422113, Maharashtra, India** is considered to be operating at an acceptable level of compliance with the requirements of the Tanzania Food, Drugs and Cosmetics (Good Manufacturing Practice Enforcement) Regulations, 2018 for manufacturing of **General Oral solid dosage in form of tablets**.

This TPIR will remain valid until 31st August, 2027 provided that the facility will remain compliant following any inspections conducted in the period.



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Part 4: References

1. TMDA (2023) Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition, Dodoma, Tanzania.
2. TMDA Good Manufacturing Practices Manual and SOPs, Tanzania Medicines and Medical Devices Authority, Dar-es-Salaam, Tanzania.
3. Tanzania Medicines and Medical Devices Act, Cap 219.
4. TMDA, Good Manufacturing Practices Enforcement Regulations (2018), Tanzania Medicines and Medical Devices, Dar-es-Salaam, Tanzania