THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TMDA

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

MYLAN LABORATORIES LIMITED, INDORE, PITHAMPUR- INDIA
PUBLIC GMP DESK ASSESSMENT REPORT

MARCH, 2025

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, Plot No. 11, 12 & 13, Special Economic Zone, Pharma Zone, Phase-II, Sector-III, Pithampur, 454775, Dist.- Dhar, Madhya Pradesh, India
Name of Unit/ block/ workshop number inspected	FDF-3, Indore, Block A and Block B
1.3 Inspection details	
Date of desk review	1st August, 2024
Date of last inspection by the SRA, WHO-PQ or EAC / SADC for production line applied at TMDA	13th to 17th September, 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

Site Master file number SMF/MLLFD3/SMF001/22 effective from 10th June, 2024 was submitted. The SMF was prepared as per requirements stipulated in the TMDA (Good Manufacturing Practice Enforcement) Regulations GN 295.

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

The facility was inspected by:

a. Pharmaceuticals and Medical Devices Agency (PMDA) on12/06/2023 – 15/06/2023.

b. World Health Organization (WHO), Geneva on 26th May 2021 and

c. European Medicine Agency (EMA) (HPRA + OGYEI) on 13-17th September, 2023.

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. State Licensing Authority, Food and Drugs Administration (Madhya Pradesh) dated 12th January, 2024. The validity period is 5 years i.e. up to 16/01/2029. The scope of authorized operations including manufacturing for sale drugs.

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 SRA/WHO-PQ/RECs

The SRA which inspected the facility was National Institute of Pharmacy and Nutrition (OGYEI), Hungary

2.4.2. Dates of inspection
13th to 17th September, 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

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

The GMP inspection report with reference No. OGYEI/29981-4/2021 from European Medicines Agency (EMA) following inspection conducted on 13th - 17th September, 2023 was submitted. This confirmed full SRA audit covering the product(s) has been performed. Subsequently, applicant submitted a copy of EudraGMP certificate with certificate No. OGYEI/29981-4/2021. The authenticity of this GMP certificate was verified through Eudra GMP database.

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

The applicant had submitted two letters dated 10/06/2024 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 10/06/2024 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, Plot No. 11, 12 & 13, Special Economic Zone, Pharma Zone, Phase-II, Sector-III, Pithampur, 454775, Dist.- Dhar, Madhya Pradesh, 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 16th September, 2027 provided that the facility will remain compliant following any inspections conducted in the period.

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