

TMDA/DMD/MCIE/F/002

REV.# 01



THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

DELPHARM MILANO S.R.L, ITALY
PUBLIC GMP DESK ASSESSMENT REPORT

Date: March, 2025



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Tanzania Medicines & Medical Devices Authority

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Part 1: General information about the company

1.1 Manufacturer's details	
Name of manufacturer/ Applicant	Delpharm Milano S.r.l - Italy/ F.Hoffmann-La Roche Limited – Switzerland
1.2 Inspected site Details	
Name & physical address of inspected manufacturing site	Name: Delpharm Milano S.r.l Physical address of the site: Via Carnevale 1 20054 Segrate Milan - Italy Tel: +39 02 9457 2310/2913 (switchboards) Fax: +39 02 9457 2066
Name of Unit/ block/ workshop number inspected	The applicant has declared the facility to have two manufacturing blocks: i) Building 30 – Solid production, pilot scale facility, quality laboratories and offices ii) Building 36 – Oral liquid production and packaging, Solid product packaging
1.3 Inspection details	
Date of desk review	24 th July, 2024
Date of last inspection by the SRA, WHO-PQ or EAC / SADC for production line applied at TMDA	This facility was inspected on 18-04-2024 by Italian Medicine Agency (ALFA – Agenzia Italiana Del Farmaco) by a competent authority of Germany, GMP Certificate No. IT/71/H/2024 was issued which is valid for three years from date of inspection. These certificates can be traced in the EudraGMP database
1.4 Brief report of the activities undertaken at the site	
Summary of the activities performed at the site	The facility is involved in for the manufacturing of oral solids in form of tablets and capsules (Cytotoxics) and liquids for internal use (hormones or substances with hormonal



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	activity), manufacture of intermediates (bulk), primary and secondary packaging and Quality Control testing.
Production lines applied at TMDA	Cytotoxic oral solid products for human use in form of film coated tablets exclusively Cellcept (Mycophenolate mofetil 500mg) film coated tablets

Part 2: Review of submitted documentary evidence

2.1. Site master file (*describe consistency of SMF as per requirements*)
Contents and layout of Site master file No. Ed.20/2024, version 16 presented complied with requirements stipulated in TFDA GMP Regulations, 2018

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

This facility was inspected on 18-04-2024 by Italian Medicine Agency (ALFA – Agenzia Italiana Del Farmaco) by a competent authority of Germany, GMP Certificate No. IT/71/H/2024 was issued which is valid for three years from date of inspection. These certificates can be traced in the EudraGMP database

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

This facility was inspected on 18-04-2024 by Italian Medicine Agency (ALFA – Agenzia Italiana Del Farmaco) by a competent authority of Germany, GMP Certificate No. IT/71/H/2024 was issued which is valid for three years from date of inspection. These certificates can be traced in the EudraGMP database

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

Not applicable, see section 2.2 of this report

2.4.1. Name of SRA/WHO-PQ/RECs

Italian Medicine Agency (ALFA – Agenzia Italiana Del Farmaco)

2.4.2. Dates of inspection
24th July, 2024



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2.4.3. Scope of inspection / List of compliant production line

Cytotoxic oral solid products for human use in form of film coated tablets exclusively Cellcept (Mycophenolate mofetil 500mg) film coated tablets

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

Not provided but this can be waived since the manufacturing facility was inspected by stringent regulatory Authority (Italian Medicine Agency (ALFA – Agenzia Italiana Del Farmaco)) and deemed GMP compliant in accordance with Art. 40 of Directive 2001/83/EC

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

The facility confirmed that there were no high-risk market complaints for the past three years, it was also noted that there are no complaints received from the Tanzania Market for the products as well for the past three years.

2.6. PQR(s) of the concerned product(s) (If products have not been registered).

This section is waived since the product applied for registration was registered before and is currently under renewal process (Queried).

2.7. Real time and Accelerated Stability studies under Zone IVb conditions (*If products have not been registered*).

This section is waived since the product applied for registration was registered before and is currently under renewal process (Queried).

2.8. Review of Aseptic processing and filling validation protocols and reports (*for sterile products*).

This is waived because the manufacturing facility applied for and was GMP certified by SRA for manufacturing of Cytotoxic oral solid products for human use in form of film coated tablets exclusively Cellcept (Mycophenolate mofetil 500mg) film coated tablets

2.9. Review of validation master plan; policy on validation qualification and calibration (If no product has been registered).



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This section is waived since the product applied for registration was registered before and is currently under renewal process (Queried).

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

The facility confirmed that there were no high-risk market complaints for the past three years, it was also noted that there are no complaints received from the Tanzania Market for the products as well for the past three years.

Part 3: Conclusion

Based on the desk assessment and evidence(s) provided Delpharm Milano S.R.L, Via Carnevale 1, 20054 Segrate, Milan - Italy 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 Cytotoxic oral solid products for human use in form of film coated tablets.

This TPIR will remain valid until 25th July, 2027, provided that the facility will remain compliant following any inspections conducted in the period.