

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



THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

RECIPHARM-BIOLÓGICI ITALIA LABORATORIES SRL, ITALY
PUBLIC GMP DESK ASSESSMENT REPORT

Date: March 2025



TMDA PUBLIC GMP DESK ASSESSMENT REPORT



Tanzania Medicines & Medical Devices Authority

TMDA/DMC/MCIE/F/002

Rev #:1

Page 1 of 3

Part 1: General information about the company

1.1 Manufacturer's details	
Name of manufacturer/ Applicant	Recipharm-Biologici Italia Laboratories S.r.l (Milan)
1.2 Inspected Site Details	
Name & physical address of inspected manufacturing site	Recipharm-Biologici Italia Laboratories S.r.l (Milan), Via Filippo Serpero No. 2, 20060 Masate (Milano), Italy
Name of Unit/ block/ workshop number inspected	Northern Body and Southern Body
1.3 Inspection details	
Date of desk assessment	02 nd August, 2024
Date of last inspection by the WLA, WHO-PQ or EAC / SADC/AMA for production line applied at TMDA	Site was last inspected from 27 th October 2021 by Italian Medicine Agency i.e. Agenzia Italiana Del Farmaco (AIFA)
1.4 Brief report of the activities undertaken at the site	
Summary of the activities performed at the site	<p>The facility was engaged in the formulations, Processing, Packing, Quality Control and Warehousing.</p> <p>The facility manufactures human medicines; (Aseptically and terminal sterilized),</p> <ul style="list-style-type: none">• Biologicals (Lyophilized powder for injection and small volume liquids)• Hormones (sterile injectables in form of small volume liquids)• General formulations (Lyophilized powder for injection and small volume liquids).
Production lines applied at TMDA	General formulations in form of small volume parenteral (SVP) (liquid ampoules)



TMDA PUBLIC GMP DESK ASSESSMENT REPORT



TMDA/DMC/MCIE/F/002
Rev #:1
Page 2 of 3

Part 2: Review of submitted documentary evidence

2.1. Site master file

A valid, dated and signed site master file (SMF) edition 17, dated 17th May, 2022 was submitted. The review of SMF confirmed that the information provided were in-line with the requirements of the Second schedule of the TMDA (Good Manufacturing Practice Enforcement) Regulations GN 295.

2.2. List of all regulatory inspections carried out in the past three (3) years.

The site was last inspected from 27th September 2024 by Italian Medicine Agency i.e. Agenzia Italiana Del Farmaco (AIFA). The inspection covered the production line applied for registration in Tanzania.

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

The valid manufacturing license No: aM17/2022 dated 27th May, 2022 was enclosed and was also confirmed to align with the license number in the certificate accessed from the Eudra GMP website.

Furthermore, a valid GMP certificate issued by Italian Ministry of Health (AIFA) based on inspection conducted from 4th – 7th April 2022 was enclosed. The certificate is valid for three (3) years from the date of inspection. This certificate was verified and confirmed to be available in the Eudra GMP website. Scope of the certificate included production line for the products applied for registration in Tanzania.

At the time of preparation of this summarized report it was confirmed in Eudra GMP data base that last inspection of the facility was conducted on 27th September, 2024 by AIFA.

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

A valid GMP certificate number IT/21/H/2022 issued by Italian Ministry of Health (AIFA) based on inspection conducted from 4 – 7 April 2022 was enclosed. The certificate was valid for three (3) years from the date of inspection.



TMDA PUBLIC GMP DESK ASSESSMENT REPORT



TMDA/DMC/MCIE/F/002

Rev #:1

Page 3 of 3

2.4.1. Name of WLA /WHO-PQ/RECs

Italian Medicines Agency i.e Agenzia Italiana Del Farmaco (AIFA).

2.4.2. Dates of inspection

The inspection conducted from 4 – 7 April 2022 by Italian Medicines Agency i.e Agenzia Italiana Del Farmaco (AIFA).

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

The scope of the manufacturing license covers general formulations (SVP), biologicals (SVP) and hormones (SVP).

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

The inspection report from Agenzia Italiana Del Farmaco (AIFA) dated 18th October, 2021 regarding inspection that was conducted from 4 – 7 October, 2021 was submitted. This confirmed full SRA audit covering the product(s) has been performed

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

TMDA's Substandard and Falsified medicines register was reviewed and it was observed that no complaints on products manufactured by this facility were reported. Moreover, no regulatory actions have been taken against this facility in the past three years.

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

TMDA's Substandard and Falsified medicines register was reviewed and it was observed that no complaints on products manufactured by this facility were reported. Moreover, no regulatory actions have been taken against this facility in the past three years

Part 3: Conclusion

Based on the desk assessment and evidence(s) provided, Recipharm-Biologici Italia Laboratories S.r.l (Milan), Via Filippo Serpero No. 2, 20060 Masate (Milano), 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



TMDA PUBLIC GMP DESK ASSESSMENT REPORT



Tanzania Medicines & Medical Devices Authority

TMDA/DMC/MCIE/F/002

Rev #:1

Page 4 of 3

Enforcement) Regulations, 2018 for manufacturing of general formulation in form of small volume parenteral (SVP) (liquid ampoules).

This TPIR will remain valid until 26th September, 2027 provided that the facility will remain compliant following any inspections conducted in the period.