THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TMDA

Tanzania Medicines & Medical Devices Authority

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

ROCHE DIAGNOSTICS GMBH, STERILE DRUG PRODUCT MANUFACTURING, SANDHOFER STR. 116, D-68305 MANNHEIM, GERMANY

PUBLIC GMP DESK ASSESSMENT REPORT

Date: March 2025

Part 1: General information about the company

1.1 Manufacturer's details	
Name of manufacturer/ Applicant	F. HOFFMAN-LA ROCHE LTD
1.2 Inspected Site Details	
Name & physical address of inspected manufacturing site	Roche Diagnostics GmbH, Sterile Drug Product Manufacturing, Sandhofer Str. 116, D-68305 Mannheim, Germany
Name of Unit/ block/ workshop number inspected	Manufacturing block
1.3 Inspection details	
Date of desk assessment	24th July, 2024
Date of last inspection by the WLA, WHO-PQ or EAC / SADC/AMA for production line applied at TMDA	The last GMP inspection was conducted on July 11th – 20th, 2024 by the US FDA.
1.4 Brief report of the activities undertaken at the site	
Summary of the activities performed at the site	Manufacturing, packaging, and quality control testing of sterile biologicals in form of lyophilized powder, solution for injection packed in vials, and prefilled syringes
Production lines applied at TMDA	1. General Pharmaceuticals (sterile) in form of lyophilized powder, solution for injection in vials, and prefilled syringes. 2. Biological medicinal products (Protein and DNA) packed in vials

Part 2: Review of submitted documentary evidence

2.1. Site master file (*describe the consistency of SMF as per requirements*)

A valid signed site master file (SMF) No: MSC-0100199, Effective from 8th August 2023 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 facility was last inspected on July 11th – 20th, 2024 by the US FDA. The facility has also been inspected by other SRAs including ANVISA, Brazil and PMDA, Japan.
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: DE_BW_01_MIA_2023_0062 issued by the Germany Health Authority (Regierungspräsidium Tübingen) on 23rd August 2023.
Moreover, a copy of valid GMP Certificate No: DE_BW_01_GMP_2023_0129 issued by the Germany Health Authority (Regierungspräsidium Tübingen) on 23rd August 2023 was enclosed. *This* Certificate was verified and confirmed to be available in the Eudra GMP website. The scope depicted in GMP certificate included production line applied for registration in Tanzania.

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 No: DE_BW_01_GMP_2023_0129 issued by the Germany Health Authority (Regierungspräsidium Tübingen) on 23rd August 2023 was enclosed. The certificate is valid for three (3) years from the date of inspection. The production lines submitted for product registration were within the scope of the certificate.

2.4.1. Name of WLA /WHO-PQ/RECs
Germany Health Authority (Regierungspräsidium Tübingen).

2.4.2. Dates of inspection

The inspection was conducted on 23rd August 2023.

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

The scope of the manufacturing license covered;

- Manufacturing of general pharmaceutical products in form of sterile products (Lyophilisates and Small-volume liquids)

- Manufacturing of General Pharmaceutical products in form of biological medicinal products (Biotechnology products/Recombinant proteins/DNA)

The facility held a valid GMP certificate and the scope of the license covered the lines applied for registration in Tanzania.

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 facility held a current GMP certificate which was verified in the Eudra GMP database and included production lines for the products marketed in Tanzania and thus was considered adequate to attest to the authenticity of the inspection conducted.

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

The complaint registers for complaints received in the years 2021 and 2022 was submitted. The register showed that complaints received were not critical and their status was closed.

Furthermore, as per the **Medicines Quality, Safety and Performance Related Issues Register No. TMDA/DMC/MCIE/R/015**, there were no product complaints or recalls of products from this facility.

Also, information related to product alerts, warnings, or product recalls could not be traced on the official websites of the SRAs. 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

The complaint registers for complaints received in the years 2021 and 2022 was submitted. The register showed that complaints received were not critical and their status was closed.
From Medicines Quality, Safety and Performance Related Issues Register No. TMDA/DMC/MCIE/R/015 SF register no complaints on products manufactured by this facility were reported with quality concerns. 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, **Roche Diagnostics Gmbh, Sterile Drug Product Manufacturing, Sandhofer Str. 116, D-68305 Mannheim, Germany** 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 **sterile and biological products in form of lyophilized powder, solution for injection in vials, and prefilled syringes.**

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