THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

BAYER BITTERFELD GmbH, BITTERFELD-WOLFEN, 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	BAYER BITTERFELD GmbH - Germany/ Bayer East Africa Limited - Kenya
1.2 Inspected site Details	
Name & physical address of inspected manufacturing site	Name: Bayer Bitterfeld GmbH Physical address of the site: Bayer Bitterfeld GmbH OT Greppin Salegaster Chaussee 1 06803 Bitterfeld-Wolfen Germany, Post Code: 06803 Province/State: Bitterfeld-Wolfen Country: Germany Contact Person: Dominic Boeth Telephone and Mobile Number: +49 3493 359101 E-mail: dominic.boeth@bayer.com
Name of Unit/ block/ workshop number inspected	Manufacturing block, unit OT Greppin
1.3 Inspection details	
Date of desk review	25th 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 17-06-2024 by Landesverwaltungsamt (LVwA) Halle (Saale), Saxony-Anhalt by a competent authority of Germany, GMP Certificate No. ST-01-GMP-2024-0027 was issued which is valid for three years from date of inspection. This certificate 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 • Manufacturing, packaging and batch certification of general pharmaceutical products for human use inform of non-sterile solid dosage form (tablets)

	• Quality control testing (physical/chemical and microbiology: non-sterility) of general pharmaceutical products for human use inform of non-sterile solid dosage form (tablets)
Production lines applied at TMDA	General pharmaceutical products for human use in the form of 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. REGS-DE12-SOP VERSION 19.0 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 17-06-2024 by Landesverwaltungsamt (LVwA) Halle (Saale), Saxony-Anhalt by a competent authority of Germany,
GMP Certificate No. ST-01-GMP-2024-0027 was issued which is valid for three years from date of inspection. This certificate 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 17-06-2024 by Landesverwaltungsamt (LVwA) Halle (Saale), Saxony-Anhalt by a competent authority of Germany,
GMP Certificate No. ST-01-GMP-2024-0027 was issued which is valid for three years from date of inspection. This certificate 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.

See section 2.2 of this report

2.4.1. Name of SRA/WHO-PQ/RECs

Landesverwaltungsamt Sachsen-Anhalt

2.4.2. Dates of inspection
17th June, 2024

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

General pharmaceutical products for human use in the form of 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

Company headed conformation letter signed by QA and dated 17/05/2024 was presented

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 is waived because the product of concern has been registered by TMDA, this implies that PQR was assessed during the dossier assessment

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

This is waived because the product of concern has been registered by TMDA, this implies that PQR was assessed during the dossier assessment

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 General pharmaceutical products for human use in the form of tablets

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

This is waived because the product of concern has been registered by TMDA, this implies that PQR was assessed during the dossier assessment

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 Bayer Bitterfeld GmbH, Bayer Bitterfeld GmbH OT Greppin Salegaster Chaussee 1 06803 Bitterfeld-Wolfen, 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 products in the form of OSD (Tablets).

This TPIR will remain valid until 24th July, 2027, provided that the facility will remain compliant following any inspections conducted in the period.