

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



THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GLAXO WELLCOME PRODUCTION, FRANCE
PUBLIC GMP DESK ASSESSMENT REPORT

13th March 2025



**TMDA PUBLIC GMP DESK ASSESSMENT
REPORT FORMAT**



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Part 1: General information about the company

1.1 Manufacturer's details	
Name of manufacturer/ Applicant	Glaxo Wellcome Production, France
Corporate address of manufacturer (if any)	Nil
1.2 Inspected site Details	
Name & physical address of inspected manufacturing site	Glaxo Wellcome Production, Z.I. de la Peyenniere, BP2 – Mayenne, 53100, France
Name of Unit/ block/ workshop number inspected	All manufacturing and packaging operations are performed in a single block
1.3 Inspection details	
Date of desk review	22 nd July 2024
Date of last inspection by the SRA, WHO-PQ or EAC / SADC for production line applied at TMDA	9 th to 13 th October 2023 National Agency for the Safety of Medicine and Health Products, France
1.4 Brief report of the activities undertaken at the site	
Summary of the activities performed at the site	The facility was engaged in the manufacturing and packaging of beta-lactam penicillin in the form of oral powder for suspension and OSD (tablets, capsules)
Production lines applied at TMDA	OSD (tablets, capsules) and oral powder for suspension

Part 2: Review of submitted documentary evidence

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

The SMF provided had no reference number for traceability, It was also not compiled as required by TFDA GMP Regulations, 2018, however, this is waived because the products have been registered. The completeness and adequacy of SMF can be taken into consideration during the next GMP application

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



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None

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

The competent Authority of Spain issued the certificate covering the OSD penicillin (tablets, capsules, and powder for oral suspension) production line that applied for GMP inspection details that were obtained from the Eudra GMP database.

- 2.4. Inspection report by other stringent medicines regulatory authority and/or that from WHO prequalification and Regional Harmonization Initiatives (whichever is applicable) carried out within the past three years for production line(s) applied at TMDA.

The inspection report was not submitted, however, the competent Authority of Spain issued the certificate covering the OSD Penicillin (tablets, capsules, and powder for oral suspension) production line , details that were obtained from the Eudra GMP database

- 2.4.1. Name of SRAWHO-PQ/RECs
National Agency for the Safety of Medicine & Health

- 2.4.2. Dates of inspection
The report was not submitted

- 2.4.3. Type of inspection (pre-registration or renewal)
GMP Renewal Inspection

- 2.4.4. Scope of inspection
OSD Penicillin (tablets, capsules) and powder for oral suspension production line

- 2.4.5. A summary of the Inspection report
The facility is considered to be operating at an acceptable level of compliance

- 2.4.6. Final conclusion of the inspection report
The facility is considered to be operating at an acceptable level of compliance with the requirements for manufacturing of penicillin products in the form of capsules and powder for oral suspension.

- 2.5. Regulatory Actions against the facility that were taken in the past three (3) years.
No regulatory action was ever taken about their quality

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



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- Since products manufactured from this site have been registered and thus this section is waived
- 2.7. Real time and Accelerated Stability studies under Zone IVb conditions (*If products have not been registered*).
Since products manufactured from this site have been registered and thus this section is waived
- 2.8. Review of Aseptic processing and filling validation protocols and reports (*for sterile products*).
Since products manufactured from this site have been registered and thus this section is waived
- 2.9. Review of Process validation protocol and reports for one of the products marketed or to be registered in the country (*If no product has been registered*).
Since products manufactured from this site have been registered and thus this section is waived
- 2.10. Review of batch manufacturing record (BMR) and master batch record including the packing and analytical part for products not yet registered.
Since products manufactured from this site have been registered and thus this section is waived
- 2.11. Market complaints in the last three years for products applied at TMDA
Since the products manufactured in this facility have been registered by the Authority and no regulatory action was ever taken with regard to their quality

Part 3: Conclusion

Based on the desk assessment and evidence(s) provided Glaxo Wellcome Production, ZI de la Peyenniere BP2 -Mayenne, 53100, France 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 beta lactam-penicillin products in form of capsules and powder for oral suspension.