THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

POLPHARMA S.A PHARMACEUTICALS WORKS, POLAND

PUBLIC GMP DESK ASSESSMENT REPORT

MARCH, 2025

Part 1: General information about the company

1.1 Manufacturer's details	
Name of Applicant	Teva Pharmaceutical Industries Ltd, Dvorah Haneviah 124, P.O. Box 3190, Tel Aviv 6944020, **Israel.** Telephone: 972-3-9267267
1.2 Inspected site Details	
Name & physical address of inspected manufacturing site	Polpharma S.A Pharmaceuticals Works, Starogard Gdanski ul. Pelplinska 19, 83-200 Starogard Gdanski, **Poland**
Name of Unit/ block/ workshop number inspected	Manufacturing Block
1.3 Inspection details	
Date of desk review	31st July, 2024
Date of last inspection by the SRA, WHO-PQ or EAC / SADC for production line applied at TMDA	7th to 10th June, 2022
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 finished dosage forms (sterile and non-sterile) • Manufacturing and distribution of active substances, medical devices, and Cosmetics • Manufacturing of investigational medicinal products • Distribution and warehousing
Production lines applied at TMDA	General formulations in form of oral solid dosage (tablets) line

Part 2: Review of submitted documentary evidence

2.1. Site master file

Site Master file number STG/SMF/001/31, effective from 27th April 2023 was submitted. The SMF was prepared as per requirements stipulated in the TMDA (Good Manufacturing Practice Enforcement) Regulations, 2018.

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

The facility was inspected by Chief Pharmaceutical Inspectorate, Poland from 7th to 10th June, 2022

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

A valid manufacturing license issued by NRA, i.e. the Chief Pharmaceutical Inspectorate, Poland, on 17th April 2024, was provided, and its scope covered the production line for the products marketed in Tanzania

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

2.4.1. Name of SRA/WHO-PQ/RECs

The SRA that inspected the facility was the Chief Pharmaceutical inspectorate, Poland

2.4.2. Dates of inspection

7th to 10th June, 2022

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

The inspected and compliant production line wasgeneral formulations (oral solid dosage) tablets line

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

Not provided, but the site was confirmed to be GMP compliant in the Eudra GMP database for the production line under the TMDA scope.

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

The applicant had not submitted a declaration confirming that there were no market complaints received in the past three years and currently, no product from this site has been registered in Tanzania

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

The applicant had not submitted a declaration confirming that there were no market complaints received in the past three years and currently, no product from this site has been registered in Tanzania.

Part 3: Conclusion

Based on the desk assessment and evidence(s) provided **Polpharma S.A Pharmaceuticals Works** located at **Starogard Gdanski ul. Pelplinska 19, 83-200 Starogard Gdanski, Poland** 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 oral solid dosage in the form of tablets.**

This TPIR will remain valid for three (3) provided that the facility will remain compliant following any inspections conducted in the period.

Part 4: References

1. TMDA (2023) Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition, Dodoma, Tanzania

2. TMDA Good Manufacturing Practices Manual and SOPs, Tanzania Medicines and Medical Devices Authority, Dar-es-Salaam, Tanzania

3. Tanzania Medicines and Medical Devices Act, Cap 219.

4. TMDA, Good Manufacturing Practices Enforcement Regulations (2018), Tanzania Medicines and Medical Devices, Dar-es-Salaam, Tanzania