THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

ACS DOBFAR S.p.A, VERONA-ITALY

PUBLIC GMP DESK ASSESSMENT REPORT

MARCH, 2025

Part 1: General information about the company

1.1 Manufacturer's details	
Name of Applicant	Arwan Pharmaceutical Industries Lebanon s.a.l., Lebanon, No. 3 Jadra Real Zone, Province of El-Chouf, Governorate of Mount Lebanon – Lebanon Tel: +961 7 996 002
1.2 Inspected site Details	
Name & physical address of inspected manufacturing site	ACS Dobfar S.p.A, Via Alessandro Fleming 2,37135 Verona, Italy
Name of Unit/ block/ workshop number inspected	AP2
1.3 Inspection details	
Date of desk review	29th July, 2024
Date of last inspection by the SRA, WHO-PQ or EAC / SADC for production line applied at TMDA	27th October, 2023
1.4 Brief report of the activities undertaken at the site	
Summary of the activities performed at the site	Manufacturing and packaging of cephalosporin powder for injection
Production lines applied at TMDA	Cephalosporin powder for injection

Part 2: Review of submitted documentary evidence

2.1. Site master file

Site Master file number V/SMF Revision no. 4, effective from 3rd April, 2024 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 the Italian Ministry of Health (AIFA) on 27th October, 2023.

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. Italian Ministry of Health (AIFA) on 27th February, 2024 was provided.

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 which inspected the facility was Italian Ministry of Health (AIFA), Italy

2.4.2. Dates of inspection

27th October, 2023

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

The inspected and compliant production lines was Cephalosporin Powder for Injection 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 TMDA scope.

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

The applicant had submitted a signed and dated letter confirming that there were no warnings, market complaints and product recalls in the past three years and that all CAPAs were appropriately implemented and closed

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

The applicant had submitted a signed and dated letter confirming that there were no warnings, market complaints and product recalls in the past three years and that all CAPAs were appropriately implemented and closed

Part 3: Conclusion

Based on the desk assessment and evidence(s) provided **ACS Dobfar S.p.A, Via Alessandro Fleming 2,37135 Verona, 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 Enforcement) Regulations, 2018 for manufacturing of **Cephalosporin Powder for Injection.**

This TPIR will remain valid for three years (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