THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

ACS DOBFAR S.p.A, TERAMO - ITALY

PUBLIC GMP DESK ASSESSMENT REPORT

Date: March, 2025

Part 1: General information about the company

1.1 Manufacturer's details	
Name of manufacturer/ Applicant	Arwan Pharmaceutical Industries Lebanon s.a.l.
1.2 Inspected Site Details	
Name & physical address of inspected manufacturing site	ACS Dobfar S.p.A, Nucleo Industriale, S. AttoS. Nicolo a Tordino, 64100 Teramo, **Italy**
Name of Unit/ block/ workshop number inspected	Building C – (For cephalosporin powder for injection) Building P – (For Penems)
1.3 Inspection details	
Date of desk assessment	31st July, 2024
Date of last inspection by the WLA, WHO-PQ or EAC / SADC/AMA for production line applied at TMDA	Site was last inspected from 4th to 8th April 2022 by Italian Ministry of Health (AIFA)
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 Cephalosporin powder for injection, Penem powder for injection and tablets
Production lines applied at TMDA	Manufacturing and packaging of sterile powder for injection i.e. (Penem powder for injection)

Part 2: Review of submitted documentary evidence

2.1. Site master file

A valid, dated and signed Site Master File (SMF) with Ref. No:'P/SMF, Revision No. 19 effective date: 9/2022 and next review date: 9/2025 was submitted. The SMF had all required information as stipulated in Good Manufacturing Practices Regulations, 2018.

2.2. List of all regulatory inspections carried out in the past three (3) years.

The site was last inspected by the Italian Ministry of Health (AIFA) from 4th to 8th April 2022. 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 with License No: Am101/2022 dated 14th July, 2022 was enclosed and was confirmed to align with the license number in the certificate accessed from the Eudra GMP website.

Furthermore, a copy of valid GMP certificate number IT/129/H/2022 issued by Italian Ministry of Health (AIFA) based on inspection conducted from 4th – 8th April 2022 was enclosed. The certificate is valid for three (3) years from the date of inspection i.e. 08.04.2022. Certificate was also verified and confirmed to be available in the Eudra GMP website. Scope depicted in the 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 number IT/129/H/2022 issued by Italian Ministry of Health (AIFA) based on inspection conducted from 4th – 8th April 2022 was enclosed. The certificate is valid for three (3) years from the date of inspection i.e. 08.04.2022. The production lines for product registration were within the scope of the certificates.

2.4.1. Name of WLA /WHO-PQ/RECs

The facility was inspected by Italian Ministry of Health (AIFA), Italy.

2.4.2. Dates of inspection

The inspection was conducted from 4th – 8th April 2022 by Italian Ministry of Health (AIFA).

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

Scope of the certificate included aseptic preparation of beta lactam powder for injection and manufacturing of non-sterile medicinal products i.e. 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

No Confirmation by senior QA representative that a full SRA audit covering meropenem powder for injection production line was provided. However, this was waived since the GMP compliance of the site was confirmed through Eudra GMP data base.

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

The applicant submitted PQR report number APQR-RPQS009 for Meropenem 1G which declared that there were no complaints or product recalls in the past three years from 2020 to 2022. Moreover, 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 applicant submitted PQR report number APQR-RPQS009 for Meropenem 1G which declared that there were no complaints or product recalls in the past three years from 2020 to 2022. Furthermore, it was verified from Medicines Quality, Safety and Performance Related Issues Register that there were no product complaints or recalls of products from this facility that have been reported to and handled by TMDA.

Part 3: Conclusion

Based on the desk assessment and evidence(s) provided, **ACS Dobfar S.p.A, Nucleo Industriale, S. AttoS. Nicolo a Tordino, 64100 Teramo, 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 **sterile beta – lactams (carbapenems) in form of dry powder for injection.**

This TPIR will remain valid until 12th December, 2027 provided that the facility will remain compliant following any inspections conducted in the period.