REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND
MEDICAL DEVICES AGENCY

TURKISH MINISTRY OF HEALTH
Turkish Medicines and Medical Devices Agency

Certificate No: TR/GMP/2022/198

CERTIFICATE OF GMP COMPLIANCE OF MANUFACTURER

Part 1

Issued following an inspection in accordance with current Good Manufacturing Practice Guidelines, and the Regulation on Manufacturing Plants of Medicinal Products for Human Use* and the Law No 1262 on Pharmaceutical and Medicinal Preparations. These regulations are in line with the requirements of Pharmaceutical Inspection Co-operation Scheme (PIC/s) and the Directives of the European Commission.

Turkish Medicines and Medical Devices Agency confirms the following:

Manufacturer's Name	: TEZ TRANS LOJİSTİK A.Ş.
Head Office / Correspondence Address	: Gebze Organize Sanayi Bölgesi 1000. Cad. No: 1023 Çayırova/KOCAELİ
Site Address	: Gebze Organize Sanayi Bölgesi 1000. Cad. No: 1023 Çayırova/KOCAELİ
Manufacturing Authorization Date	: 30/10/2018
Manufacturing Authorization Number	: TR/SAY/2018/14

Has been inspected in accordance with current Good Manufacturing Practice Guidelines, the Regulation on Manufacturing Plants of Medicinal Products for Human Use, the Law No 1262 on Pharmaceutical and Medicinal Products.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 13/05/2022, it is considered that it complies with the requirements of Good Manufacturing Practice (GMP).

This certificate reflects the status of the manufacturing site at the time of the inspection, and Turkish Medicines and Medical Devices Agency should be consulted to verify compliance of the manufacturing site with GMP requirements if more than 3 years have elapsed since the date of inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified by Turkish Medicines and Medical Devices Agency upon request.

**This regulation is aligned with European Union Directive Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use, and Directive 2001/83/EC on the Community code relating to medicinal products for human use.*

30/06/2022

PhD Pharm. Sevil AZAK SUNGUR
Vice President of the Agency

TR/GMP/2022/198

Address: Söğütözü Mahallesi 2176. Sok. No:5 06520 Çankaya/ANKARA
Tel: (0312) 218 30 00 Fax: (0312) 218 34 60

REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND
MEDICAL DEVICES AGENCY

TURKISH MINISTRY OF HEALTH
Turkish Medicines and Medical Devices Agency

Part 2

■ Human Medicinal Products *

1 MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS*	
If the company is engaged in manufacture of products with special requirements, e.g. radiopharmaceuticals or products containing penicillin, sulphanomides, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients, this should be stated under the relevant product type and dosage form.	
1.5	**Packaging**
	1.5.2 Secondary packaging

Any restrictions or clarifying remarks related to the scope of this certificate *:
1.5.2: Applicable to storage, insertion/change of prospectus, ink-jet printing, labeling, boxing and data coding.

2 IMPORTATION OF MEDICINAL PRODUCTS*	
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Any restrictions or clarifying remarks related to the scope of this certificate *:
2.3.1: Applicable to storage, insertion/change of prospectus, ink-jet printing, labeling, boxing and data coding.

30/06/2022

TR/GMP/2022/198

PhD Pharm. Sevil AZAK SUNGUR
Vice President of the Agency

Address: Söğütözü Mahallesi 2176. Sok. No:5 06520 Çankaya/ANKARA
Tel: (0312) 218 30 00 Fax: (0312) 218 34 60