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/2020/82

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	: MOLTEK MOLEKÜLER TEKNOLOJİ ARAŞTIRMA SAN. TİC. A.Ş.
Head Office / Correspondence Address	: Gebze Organize Sanayi Bölgesi Şahabettin Bilgisu Caddesi No:611/1 Gebze/KOCAELİ
Site Address	: Gebze Organize Sanayi Bölgesi Şahabettin Bilgisu Caddesi No:611/1 Gebze/KOCAELİ
Manufacturing Authorization Date	: 04.05.2009
Manufacturing Authorization Number	: 2009/05

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 18-20/03/2019, 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.*

Digitally signed by Bolea Petru
Date: 2021.07.09 10:19:26 EEST
Reason: MoldSign Signature
Location: Moldova

Eray KAPLAN
Vice President of Inspectorate

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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.	
1.1	**Sterile Products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids It is valid for the manufacturing of the radiopharmaceutical with the name Moltek FDG (F18) FluoroDeoxyGlucose.
	1.1.3 Batch certification
1.6	**Quality control testing**
	1.6.1 Microbiological (sterility)

20/03/2020 TR/GMP/2020/82

Eray KAPLAN
Vice President of Inspectorate