Bulgarian Drug Agency

CERTIFICATE NUMBER: ***№ BG/GMP/2025/300***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Bulgaria confirms the following:
The manufacturer: ***Eczacibasi Monrol Nukleer Urunler Sanayi Ve Ticaret A.S.***
Site address: ***Tubitak Mam Tecnopark, Gebze, 41470, Türkiye***
OMS Organisation Id. / OMS Location Id.: ***ORG-100022754*** / ***LOC-100031455***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-08-28***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that 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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids Special Requirements 5 Radiopharmaceuticals
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids Special Requirements 5 Radiopharmaceuticals
	1.1.3 Batch certification
1.4	**Other products or manufacturing activity**
	1.4.3 Other: Radiopharmaceuticals(en)
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

1.1.1.4 it is applicable to the production activities of MON.FDG (18F) solution for i.v. injection, vial; MON.MIBG-I131 Diagnostic 9-120 MBq/mL solution for i.v. injection, vial; MON.MIBG-I131 Therapeutic 370-3700 MBq solution for i.v. injection, vial; MON.MIBG-I123 Diagnostic 40-820 MBq solution for i.v. injection, vial; 1.1.2.3 it is applicable to the production activities MON.LUTEC 37 GBq/mL radiopharmaceutical precursor solution; Lutetium Chloride (Lu-177) radiopharmaceutical precursor solution (nca). Based on risk assessment the validity of the certificate is two years.

2025-01-27

Name and signature of the authorised person of the Competent Authority of Bulgaria

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Bulgarian Drug Agency
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