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/2021/92

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	: Eczacıbaşı Monrol Nükleer Ürünler San. ve Tic. A.Ş.
Head Office / Correspondence Address	: TÜBİTAK MAM Teknoparkı Gebze / KOCAELİ / TURKEY
Site Address	: Barış Mahallesi Dr. Zeki Acar Caddesi No:1 (TÜBİTAK MAM Teknoparkı) Gebze / KOCAELİ / TURKEY
Manufacturing Authorization Date	: 23/03/2021
Manufacturing Authorization Number	: TR/RFT/2020/1-2

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 13-15.08.2018, 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.*

Ferhat GÜNGÖR
Vice President of Inspectorate

Address: Söğütözü Mahallesi 2176. Sok. No:5 06520 Çankaya/ANKARA
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Part 2

Certificate No: TR/GMP/2021/92

■ 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 - Solution for injection Special requirement - Radiopharmaceutical
	1.1.2 Terminally sterilized (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids - Solution for injection Special requirement - Radiopharmaceutical
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell - Capsule, hard Special requirement - Radiopharmaceutical 1.2.1.6 Liquids for internal use - Oral solution Special requirement - Radiopharmaceutical
	1.2.2 Batch certification
1.4	**Other products or manufacturing activity**
	1.4.1 Other products 1.4.1.3 Other *(....free text)* - Active substance / excipient manufacturing
	1.4.3 Others *(....free text)*
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.6 Liquids for internal use
	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

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Any restrictions or clarifying remarks related to the scope of this certificate:

- 1.1.1.4: Valid for "MON.MIBG-1231-TANI 40-820 MBq I.V. Vial with Solution for injection", "MON.FDOPA (18F) I.V. Vial with Solution for injection", "MON.LUTEC 37 GBq/ml Radiopharmaceutical Precursor, Solution ", "MON.FDG (18F) IV Vial with Solution for injection (Fluorodeoxy glucose)", "MON.GALYUM-67 74 MBq/ml I.V. Vial with Solution for injection (Gallium-67 Citrate)", "MON.TALYUM-201 I.V. Vial with Solution for injection (Thallium chloride) 37 MBq/ml", "MON.MIBG-131I TANI 9-120 MBq/ml IV Vial with Solution for injection (131I), "MON.MIBG-131I-TEDAVİ 370-3700 MBQ I.V. Vial with Solution for injection", "MON.TEK 99Mo/99mTc Generator (Sodium Molybdate (99Mo) (Sodium Pertechnetate (99Tc))".
- 1.1.2.3 Solution for injection: Valid for the product named "Lutetium Chloride (Lu-177) Radiopharmaceutical Precursor, Solution (NCA)" in vial form.
- 1.1.3: Also valid for cold kits named "MON.DMSA KIT 1.0 mg vial containing lyophilized powder for IV injection", "MON.DTPA KIT 35.0 mg vial containing lyophilized powder for IV injection", "MON.MDP KIT 10 mg vial containing lyophilized powder for IV injection" and "MON. .MIBI KIT 1.0 mg vial containing lyophilized powder for IV injection" produced in the Mefar İlaç San. A.Ş..
- 1.2.1.1: Valid for the manufacturing of ""MON.İYOT-131 0,37-7400 MBq (10µCi-200mCi) Oral Capsule (Sodium Iodide-131I)".
- 1.2.1.6: Valid for "MON.İYOT-131 74-18500 MBq Vial Containing Oral Solution (Sodium Iodide (131I))".
- 1.4.1.3 Active substance / excipient manufacturing: Valid for the manufacturing of "Mannose triflate bulk" and "Lutetium (Lu-177) Chloride" active substance.
- 1.4.3: Valid for "The activity of marking radiopharmaceutical cold kits with Technetium Sodium Pertechnetate obtained from Mo99 / Tc99m generator under aseptic conditions", "Manufacturing in the cell that will be used as the 2nd cell for the manufacturing of MON.İYOT-131 and in the cell to be used for the manufacturing of MON.MIBG-131I solution for injection in the new area deemed appropriate as a result of the audit conducted on 31.01.2013 for the manufacturing of MON.FDG (18F) I.V. vial containing solution for injection".
- 1.6.1: Also valid for cold kits named "MON.DMSA KIT 1.0 mg vial containing lyophilized powder for IV injection", "MON.DTPA KIT 35.0 mg vial containing lyophilized powder for IV injection", "MON.MDP KIT 10 mg vial containing lyophilized powder for IV injection" and "MON.MIBI KIT 1.0 mg vial containing lyophilized powder for IV injection produced in the Mefar İlaç San. A.Ş..
- 1.6.3: Also valid for cold kits named "MON.DMSA KIT 1.0 mg vial containing lyophilized powder for IV injection", "MON.DTPA KIT 35.0 mg vial containing lyophilized powder for IV injection", "MON.MDP KIT 10 mg vial containing lyophilized powder for IV injection" and "MON.MIBI KIT 1.0 mg vial containing lyophilized powder for IV injection produced in the Mefar İlaç San. A.Ş..

The validity period of the certificate has been extended in line with the E-24931227-020-3664 Authority Approval dated 03/02/2021, and this certificate is valid until 31/12/2021.

26/03/2021

TR/GMP/2021/91

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