Bulgarian Drug Agency

CERTIFICATE NUMBER : ***№ BG/GMP/2021/180***

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 :***Eczacibaşi Monrol Nükleer Ürünler Sanayi ve Ticaret A.S.***
Site address :***TÜBİTAK MAM, Teknoparki, Gebze, Kocaeli, 41470, Turkey***

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 .

Is an excipient manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-04-29*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]
- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC .
- An appropriate level of GMP as referred to in Article 46(f) of Directive 2001/83/EC

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. 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.

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

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

Part 2

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: active substance/excipient(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)

It has been distant inspection for the following manufacturing activities: MON.FDG (18F) vial containing solution for IV Injection; MON.MIBG - I131 Diagnostic 9 -120 MBq/mL vial containing solution for IV Injection; MON.MIBG - I131 Therapeutic 370 -3700 MBq vial containing solution for IV Injection; MON.MIBG - I123 Diagnostic 40 -820 MBq vial containing solution for IV Injection; MON.LUTEC 37 GBq/mL radiopharmaceutical precursor solution; Lutetium Chloride (Lu-177) Radiopharmaceutical Precursor Solution (NCA). Only Quality control testing /1.6.1 Microbiological: sterility and 1.6.3. Chemical/Physical for Cold kits, Lyophilized powder.

2021-06-10

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

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Bulgarian Drug Agency
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