World Class Medicines for

CANCER TREATMENT

Now in Bangladesh

MEDICINES AUTHORITY

IN012/08 Appendix 01 Version 1

Certificate No: **MT/028HM/2020**

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

The Medicines Authority of Malta confirms the following:

The manufacturer: **Eskayef Pharmaceuticals Limited – Rupganj Plant**
Site address: **Oncology Unit, Sterile Facility, Murapara, Rupganj, Narayanganj, 1464, Bangladesh**

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 transposed in the following national legislation: **Art. 101A (10) of the Medicines Act (Chapter 458 of the Laws of Malta)**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **12th – 17th October 2019** it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[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.

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.

20th August 2020

Dr. Mark Cilia
Director Inspectorate & Enforcement Directorate
Medicines Authority
Tel: 00356 234 39 119
Fax: 00356 234 39 161

1 The certificate referred to at paragraph 111(5) of Directive 2001/83/EC is also applicable to importers.
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.

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