Certificate No: **MT/052HM/2023**

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 **Beacon Cephalosporin Limited**
Site address **Kathuli, Bhaluka, Mymensingh 2240, 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 **20th -24th January 2023**, it is considered that it complies with the Good Manufacturing Practice requirements[1] referred to in 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.

22nd December 2023 .....

Dr. Mark Cilia[1]
Director
Inspectorate & Enforcement Directorate
Malta Medicines Authority
Tel: 00356 234 39 119

[1] The signature, date and contact details should appear on each page of the certificate.

1 The certificate referred to in 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

Part 2

❑ Human Medicinal Products*	
1 MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS *	
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 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality Control testing**
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate*:
Secondary packaging is restricted to line 3. Intermediates of the above products are included in scope.
This certificate is limited in scope to products intended for EU/EEA markets.

22nd December 2023 .....

Dr. Mark Cilia[1]
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