MALTA MEDICINES AUTHORITY

IN012/08 Appendix 01 Version 1

Certificate No: MT/030HW/2021

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 **Ilko Ilac San. ve Tic. AS**
Site address **3 Osb Buyuk Kayacik Mah Kuddusi Cad 23 Sok No 1 Selcuklu Konya 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 transposed in the following national legislation: **Article 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 the **2nd – 7th August 2021**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[3]

3 These requirements fulfil the GMP recommendations of WHO.

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.

27th October 2021

Dr Mark Cilia[1]
Director Inspectorate
& Enforcement Directorate
Medicines Authority
Tel: 00356 234 39 119
Fax: 00356 234 39 161

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 1.2.1.8 Other solid dosage forms: pellets 1.2.1.11 Semi-solids 1.2.1.13 Tablets
1.5	**Packaging** *1.5.1 Primary packing* 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms 1.5.1.11 Semi-solids: pellets 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:
This certificate is limited in scope to medicinal products (tablets, capsules, pellets and semi-solids) intended for the EU/EEA market.

27th October 2021

Dr Mark Cilia[1]
Director Inspectorate & Enforcement Directorate
Medicines Authority
Tel: 00356 234 39 119
Fax: 00356 234 39 161

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