耳爾他

AWTORITÀ DWAR IL-MEDIĊINI

Certificate No: 1

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

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

Site address

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: **Medicines Act 2003 Part III Title II Articles 42 and 102**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on it is considered that it complies with the Good Manufacturing Practice requirements' referred to in the principles of GMP for active substances' referred to in Article 47 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 [redacted] have elapsed since the date of that inspection, after which time the issuing authority should be consulted. This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified with the issuing authority.

[redacted]

14th April 2015

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Director Inspectorate and Enforcement Directorate
Medicines Authority
Tel:

Part 2

Manufacture of active substances. Names of substances subject to inspection:

14th April 2015

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Director Inspectorate and Enforcement Directorate
Medicines Authority
Tel: 00356 234 39 119
@gov.mt

[1]These requirements fulfil the GMP recommendations of WHO