

IN012/07 Appendix 01

Certificate No: MT/019HM/2013

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 **Sterling Chemical Malta Ltd.**

Site address **HF51 Hal Far Industrial Estate, Birzebbugia BBG3000**

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 27th August 2013, it is considered that it complies with the Good Manufacturing Practice requirements¹ referred to in The principles of GMP for active substances³ referred to in Article 47 of Directive 2001/83/EC.

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.

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.

10th September 2013



Mark Cilia¹

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Medicines Authority

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