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Pharmaceutical Services Ministry Of Health

CERTIFICATE NUMBER:

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 as amended

The competent authority of Cyprus confirms the following:
The manufacturer: [1]
Site address: [1]

DUNS Number: [2]

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:
PART IV, Chapters A and B of the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law No 70(I) of 2001, as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on , it is considered that it complies with :

- The principles of GMP for active substances [3] 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 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.

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[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database*

[3] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

PHARMACEUTICAL SERVICES ★ REPUBLIC OF CYPRUS ★ MINISTRY OF HEALTH

Part 2

Any restrictions related to the scope of this certificate :

The Inspection findings concern only the manufacturing of the Active Substanc

Name and signature of the authorised person of the Competent Authority of Cyprus