LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

瑞典

瑞 表

Medical Products Agency

CERTIFICATE NUMBER:

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER (1)

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Sweden 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 .

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 EudraGMP. If it does not appear, please contact the issuing authority.

(1) The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

(3) These requirements fulfil the GMP recommendations of WHO.

LÄKEMEDELSVERKET · MEDICAL PRODUCTS AGENCY ·

Part 2

1 MANUFACTURING OPERATIONS	
1.6	**Quality Control Testing**
	1.6.3 Chemical/Physical

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

(en)

(en)

(en)

(en)

(en)

(en)

(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance :

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : other peptide synthesis

Active Substance :

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : other peptide synthesis

Active Substance :

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : other peptide synthesis

Active Substance :

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : other peptide synthesis

Active Substance :

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : other peptide synthesis

Active Substance :

3.1	**Manufacture of Active Substance by Chemical Synthesis**

	3.1.4 Other : other peptide synthesis

Active Substance :

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.4 Other : other peptide synthesis

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

Medical Products Agency
Tel:
Fax

LÄKEMEDELSVERKET · MEDICAL PRODUCTS AGENCY ·