Health Care Inspectorate - Pharmaceutical Affairs and Medical Technology

CERTIFICATE NUMBER: *NL/H 15/1005353*

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
Art. 15 of Directive 2001/20/EC

The competent authority of Netherlands confirms the following:
The manufacturer: ***Academisch Medisch Centrum***
Site address: ***Meibergdreef 9, Amsterdam, 1100DD, Netherlands***

Has been inspected under the national inspection programme in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC transposed in the following national legislation:
Art. 100 of the Medicines Act
Art. 100 of the Medicines Act

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2015-10-01*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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.*

[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.*

Part 2

Human Medicinal Products Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.2 Batch certification

1.5	**Packaging**
	1.5.2 Secondary packing
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell Special Requirements 1 B-lactam Antibiotics 2 Other highly sensitising antibiotics 7 Other 1.5.1.2 Capsules, soft shell Special Requirements 1 B-lactam Antibiotics 2 Other highly sensitising antibiotics 7 Other 1.5.1.3 Chewing gums Special Requirements 1 B-lactam Antibiotics 2 Other highly sensitising antibiotics 7 Other 1.5.1.8 Other solid dosage forms Special Requirements 1 B-lactam Antibiotics 2 Other highly sensitising antibiotics 7 Other 1.5.1.12 Suppositories Special Requirements 1 B-lactam Antibiotics 2 Other highly sensitising antibiotics 7 Other 1.5.1.13 Tablets Special Requirements 1 B-lactam Antibiotics 2 Other highly sensitising antibiotics 7 Other 1.5.1.14 Transdermal patches Special Requirements 1 B-lactam Antibiotics 2 Other highly sensitising antibiotics 7 Other

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

4. Other Activities - Active Substances :

This GMP certificate is restricted to manufacturing activities with investigational medicinal products

2015-10-08

Inspectie voor de Gezondheidszorg
Ministerie van Volksgezondheid, Welzijn en Sport
Rijksoverheid

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

Dr. Annigje Rietveld
Health Care Inspectorate - Pharmaceutical Affairs and Medical Technology
Tel: ***+31 88 1205000***
Fax ***+31 88 1205001***