

GMP- Certificate Nr: NL/H 09/0001

PUBLIC HEALTH SUPERVISORY SERVICE
HEALTH CARE INSPECTORATE



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 competent authority of The Netherlands confirms the following:

The manufacturer Eurosequence B.V.
Site address L.J. Zielstraweg 1
 9713 GX Groningen
 The Netherlands

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. 101847 EL, in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: The medicines Act, article 100.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 8 July 2008, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/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, after which time the issuing authority should be consulted.

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

Issue Date: 12 January, 2009
Signature:

A large, stylized handwritten signature in black ink, appearing to be 'O. Jellema', written over the signature line.

O. Jellema
Inspector, Health Care Inspectorate, The Netherlands
+ 31 70 3405053

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Part 2

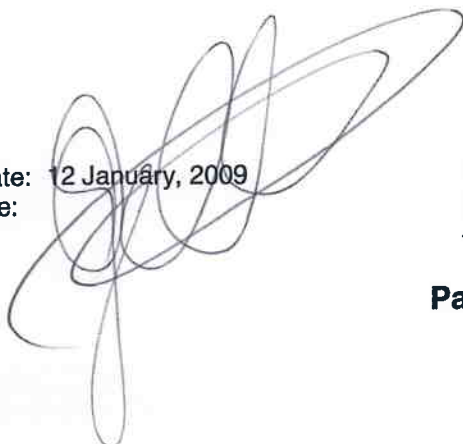
<input checked="" type="checkbox"/> Human Medicinal Products	
<input type="checkbox"/> Veterinary Medicinal Products	
<input checked="" type="checkbox"/> Human Investigational Medicinal Products	for phase I, II, III clinical trials

1.6	Quality control testing	Yes	No
		<input checked="" type="checkbox"/>	<input type="checkbox"/>
	1.6.1 Microbiological: sterility	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.6.2 Microbiological: non-sterility	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.6.3 Chemical/Physical	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	1.6.4 Biological	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Any restrictions or clarifying remarks related to the scope of this certificate:

Amino Acid Analysis and Sequence Analysis of proteins and peptides and related HPLC techniques and sample preparations.

Issue Date: 12 January, 2009
Signature:



O. Jellema
Inspector, Health Care Inspectorate, The Netherlands
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