Safeguarding public health

Certificate No: **GMP 16699/8405-0005**

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A CONTRACT LABORATORY

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC and Art. 15 of Directive 2001/20/EC.

The competent authority of the United Kingdom confirms the following:

The contract laboratory	**CEMAS**
Site address	**Glendale Park** **Fernbank Road** **North Ascot** **Berkshire** **SL5 8BJ**

Has been inspected under the national inspection programme in connection with manufacturing/marketing authorisation(s) listing the company as a site of QC testing in accordance with Art. 40 of Directive 2001/83/ECand Art. 13 of Directive 2001/20/EC transposed in the following national legislation:
The Medicines Act 1968 as amended and The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031).

From the knowledge gained during inspection of this contract laboratory, the latest of which was conducted on **27 February 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 contract quality control testing 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.

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Medicines and Healthcare products Regulatory Agency
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T 020 7084 2000 F 020 7084 2353 www.mhra.gov.uk

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Part 2

Human Medicinal Products			
1.6	**Quality control testing**		
	1.6.1	Microbiological: sterility	Not Authorised
	1.6.2	Microbiological: non-sterility	Not Authorised
	1.6.3	Chemical/Physical	Authorised
	1.6.4	Biological	Not Authorised

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

None

Name of the authorised person of the Competent Authority of the United Kingdom;

Mary Baynes
Inspector
Medicines and Healthcare products Regulatory Agency
Mary.baynes@mhra.gsi.gov.uk

Date: 15 September 2008