

Certificate No: GMP/IMP 16776/8489-0007

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. 80(5) of Directive 2001/82/EC as amended and Art. 15 of Directive 2001/20/EC.

The competent authority of the United Kingdom confirms the following:

The contract laboratory	More dun Scientific Ltd
Site address	Pentlands Science Park Bush Loan Penicuik Nr Edinburgh EH26 0PZ

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/EC and Art. 44 of Directive 2001/82/EC/ and Art. 13 of Directive 2001/20/EC transposed in the following national legislation: *The Medicines Act 1968 as amended and The Current Veterinary Medicines Regulations/ 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 **30 September 2008**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC and Directive 91/412/EEC.

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.

Safeguarding public health



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Part 2

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

Mary.baynes@mhra.gsi.gov.uk

Date: 07 November 2008

