

## Safeguarding public health

**MHRA**

Certificate No: UK GMP 22578 Insp GMP/IMP 22578/30444-0004

# Medicines and Healthcare products Regulatory Agency

## 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 United Kingdom confirms the following:

The manufacturer	Keane Analytical Limited
Site address	VALLUM FARM EAST WALLHOUSES MILITARY ROAD NEWCASTLE-UPON-TYNE NE18 0LL UNITED KINGDOM

Has been inspected in connection with Manufacturing and/or Marketing Authorisation(s) listing the company as a site of QC testing, in accordance with Art. 111(1) of Directive 2001/83/EC (or Article 80(1) of Directive 2001/82/EC) transposed in the following national legislation: For human medicines 'The Medicines Act 1968 as amended'; for veterinary medicines 'The current Veterinary Medicines Regulations'; for investigational medicinal products 'The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)'.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 05/02/2013, 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.





**Part 2**

Human Medicinal Products

**1. MANUFACTURING OPERATIONS**

**1.1 Sterile products**

	1.1.1	<i>Aseptically prepared (list of dosage forms)</i>	
	1.1.1.1	Large volume liquids	Not Authorised
	1.1.1.2	Lyophilisates	Not Authorised
	1.1.1.3	Semi-solids	Not Authorised
	1.1.1.4	Small volume liquids	Not Authorised
	1.1.1.5	Solids and implants	Not Authorised
	1.1.1.6	Other aseptically prepared products	Not Authorised
		<i>Not Authorised</i>	
	1.1.2	<i>Terminally sterilised (list of dosage forms)</i>	
	1.1.2.1	Large volume liquids	Not Authorised
	1.1.2.2	Semi-solids	Not Authorised
	1.1.2.3	Small volume liquids	Not Authorised
	1.1.2.4	Solids and implants	Not Authorised
	1.1.2.5	Other terminally sterilised prepared products	Not Authorised
		<i>Not Authorised</i>	
	1.1.3	Batch certification only	Not Authorised

