

**Safeguarding public health**

**MHRA**

RESTRICTED – COMMERCIAL  
Head Of Regulatory Affairs  
ELPHINSTONE RESEARCH CENTRE  
ELPHINSTONE RESEARCH CENTRE  
TRANENT  
EDINBURGH  
EH33 2NE  
UNITED KINGDOM

**Medicines and Healthcare products Regulatory Agency**  
Market Towers 1 Nine Elms Lane London SW8 5NQ  
T 020 7084 2000 F 020 7084 2353 [www.mhra.gov.uk](http://www.mhra.gov.uk)

An executive agency of the Department of Health



## Safeguarding public health



**MHRA**

Certificate No: UK MIA(IMP) 24616 Insp GMP/IMP 24616/25448-0003

# Medicines and Healthcare products Regulatory Agency

## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

### Part 1

Issued following an inspection in accordance with Art. 15 of Directive 2001/20/EC

The competent authority of the United Kingdom confirms the following:

The manufacturer	ELPHINSTONE RESEARCH CENTRE
Site address	ELPHINSTONE RESEARCH CENTRE TRANENT EDINBURGH EH33 2NE UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA(IMP) 24616 in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation:  
*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 26/11/2007, 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 Investigational Medicinal Products for phase I, II, III clinical trials

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



<b>1.2 Non-sterile products</b>	
1.2.1	<i>Non-sterile products (list of dosage forms)</i>
1.2.1.1	Capsules, hard shell Authorised
1.2.1.2	Capsules, soft shell Authorised
1.2.1.3	Chewing gums Not Authorised
1.2.1.4	Impregnated matrices Authorised
1.2.1.5	Liquids for external use Authorised
1.2.1.6	Liquids for internal use Authorised
1.2.1.7	Medicinal gases Not Authorised
1.2.1.8	Other solid dosage forms Not Authorised
1.2.1.9	Pressurised preparations Not Authorised
1.2.1.10	Radionuclide generators Not Authorised
1.2.1.11	Semi-solids Authorised
1.2.1.12	Suppositories Authorised
1.2.1.13	Tablets Not Authorised
1.2.1.14	Transdermal patches Authorised
1.2.1.15	Intraruminal devices Not Authorised
1.2.1.16	Veterinary premixes Not Authorised
1.2.1.17	Other non-sterile medicinal product Not Authorised
1.2.2	<i>Batch certification only</i> Not Authorised
<b>1.3 Biological medicinal products</b>	
1.3.1	<i>Biological medicinal products</i>
1.3.1.1	Blood products Authorised
1.3.1.2	Immunological products Authorised
1.3.1.3	Cell therapy products Not Authorised
1.3.1.4	Gene therapy products Not Authorised
1.3.1.5	Biotechnology products Authorised
1.3.1.6	Human or animal extracted products Authorised
1.3.1.7	Other biological medicinal products Not Authorised



1.3.2	<i>Batch certification only (list of product types)</i>	
	1.3.2.1 Blood products	Not Authorised
	1.3.2.2 Immunological products	Authorised
	1.3.2.3 Cell therapy products	Not Authorised
	1.3.2.4 Gene therapy products	Not Authorised
	1.3.2.5 Biotechnology products	Authorised
	1.3.2.6 Human or animal extracted products	Not Authorised
	1.3.2.7 Other biological medicinal products	Authorised
<i>Not Specified</i>		
<b>1.4</b>	<b>Other products or manufacturing activity</b>	
1.4.1	<i>Manufacture of:</i>	
	1.4.1.1 Herbal products	Authorised
	1.4.1.2 Homoeopathic products	Not Authorised
	1.4.1.3 Biological active starting materials	Not Authorised
	1.4.1.4 Other	Not Authorised
1.4.2	<i>Sterilisation of active substances/excipients/finished product:</i>	
	1.4.2.1 Filtration	Authorised
	1.4.2.2 Dry heat	Not Authorised
	1.4.2.3 Moist heat	Not Authorised
	1.4.2.4 Chemical	Not Authorised
	1.4.2.5 Gamma irradiation	Not Authorised
	1.4.2.6 Electron beam	Not Authorised
1.4.3	Other	Not Authorised



1.5 Packaging only		
1.5.1	<i>Primary packaging</i>	
1.5.1.1	Capsules, hard shell	Authorised
1.5.1.2	Capsules, soft shell	Authorised
1.5.1.3	Chewing gums	Not Authorised
1.5.1.4	Impregnated matrices	Authorised
1.5.1.5	Liquids for external use	Authorised
1.5.1.6	Liquids for internal use	Authorised
1.5.1.7	Medicinal gases	Not Authorised
1.5.1.8	Other solid dosage forms	Authorised
1.5.1.9	Pressurised preparations	Not Authorised
1.5.1.10	Radionuclide generators	Not Authorised
1.5.1.11	Semi-solids	Authorised
1.5.1.12	Suppositories	Not Authorised
1.5.1.13	Tablets	Not Authorised
1.5.1.14	Transdermal patches	Authorised
1.5.1.15	Intraruminal devices	Not Authorised
1.5.1.16	Veterinary premixes	Not Authorised
1.5.1.17	Other non-sterile medicinal products	Not Authorised
1.5.2	Secondary packaging	Authorised
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	Authorised



## 2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products		
2.1.1	Microbiological: sterility	Not Authorised
2.1.2	Microbiological: non-sterility	Not Authorised
2.1.3	Chemical/Physical	Authorised
2.1.4	Biological	Authorised
2.2 Batch certification of imported medicinal products		
2.2.1	<i>Sterile Products</i>	
	2.2.1.1 Aseptically prepared	Authorised
	2.2.1.2 Terminally sterilised	Authorised
2.2.2	Non-sterile Products	Authorised
2.2.3	<i>Biological medicinal products</i>	
	2.2.3.1 Blood products	Authorised
	2.2.3.2 Immunological product	Authorised
	2.2.3.3 Cell therapy products	Not Authorised
	2.2.3.4 Gene therapy products	Not Authorised
	2.2.3.5 Biotechnology products	Authorised
	2.2.3.6 Human or animal extracted products	Authorised
	2.2.3.7 Other biological medicinal products	Not Authorised
2.2.4	<i>Other importation activities</i>	
	2.2.4.1 Radiopharmaceuticals/Radionuclide generators	Not Authorised
	2.2.4.2 Medicinal gases	Not Authorised
	2.2.4.3 Herbal products	Authorised
	2.2.4.4 Homoeopathic products	Not Authorised
	2.2.4.5 Biological active starting materials	Not Authorised
	2.2.4.6 Other	Not Authorised





**Manufacture of active substance. Names of substances subject to inspection:**





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

The biological aspects on the GMP certificate were covered by Dr K Page at a separate inspection on 14-15 January 2008.

1. Building(s)/Area(s)
2. Room(s)
3. Line(s) Equipment(s)
4. QC testing
5. Medicinal Product(s)/IMP(s)

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

**Date: 07/03/2008**

