

Safeguarding public health



MHRA

Certificate No: UK GMP 35210 Insp GMP 35210/935445-0001

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	WUXI APTEC INCORPORATED
Site address	4751 LEAGUE ISLAND BLVD PHILADELPHIA PA 19112 UNITED STATES

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 30/04/2009, 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



1.2 Non-sterile products	
1.2.1	<i>Non-sterile products (list of dosage forms)</i>
1.2.1.1	Capsules, hard shell Not Authorised
1.2.1.2	Capsules, soft shell Not Authorised
1.2.1.3	Chewing gums Not Authorised
1.2.1.4	Impregnated matrices Not Authorised
1.2.1.5	Liquids for external use Not Authorised
1.2.1.6	Liquids for internal use Not 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 Not Authorised
1.2.1.12	Suppositories Not Authorised
1.2.1.13	Tablets Not Authorised
1.2.1.14	Transdermal patches Not 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
	<i>Not Authorised</i>
1.2.2	<i>Batch certification only</i> Not Authorised
1.3 Biological medicinal products	
1.3.1	<i>Biological medicinal products</i>
1.3.1.1	Blood products Not Authorised
1.3.1.2	Immunological products Not 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 Not Authorised
1.3.1.6	Human or animal extracted products Not Authorised
1.3.1.7	Other biological medicinal products Not Authorised
	<i>Not Authorised</i>





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	Not 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	Not Authorised
	1.3.2.6 Human or animal extracted products	Not Authorised
	1.3.2.7 Other biological medicinal products	Not Authorised
<i>Not Authorised</i>		
1.4	Other products or manufacturing activity	
1.4.1	<i>Manufacture of:</i>	
	1.4.1.1 Herbal products	Not 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
<i>Not Authorised</i>		
1.4.2	<i>Sterilisation of active substances/excipients/finished product:</i>	
	1.4.2.1 Filtration	Not 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
	<i>Not Authorised</i>	



1.5 Packaging only		
1.5.1	<i>Primary packaging</i>	
	1.5.1.1 Capsules, hard shell	Not Authorised
	1.5.1.2 Capsules, soft shell	Not Authorised
	1.5.1.3 Chewing gums	Not Authorised
	1.5.1.4 Impregnated matrices	Not Authorised
	1.5.1.5 Liquids for external use	Not Authorised
	1.5.1.6 Liquids for internal use	Not Authorised
	1.5.1.7 Medicinal gases	Not Authorised
	1.5.1.8 Other solid dosage forms	Not Authorised
	1.5.1.9 Pressurised preparations	Not Authorised
	1.5.1.10 Radionuclide generators	Not Authorised
	1.5.1.11 Semi-solids	Not Authorised
	1.5.1.12 Suppositories	Not Authorised
	1.5.1.13 Tablets	Not Authorised
	1.5.1.14 Transdermal patches	Not 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
	<i>Not Authorised</i>	
1.5.2	Secondary packaging	Not Authorised
1.6 Quality control testing		
1.6.1	Microbiological: sterility	Not Authorised
1.6.2	Microbiological: non-sterility	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	Not Authorised
2.1.4	Biological	Not Authorised
2.2 Batch certification of imported medicinal products		
2.2.1	<i>Sterile Products</i>	
	2.2.1.1 Aseptically prepared	Not Authorised
	2.2.1.2 Terminally sterilised	Not Authorised
2.2.2	Non-sterile Products	Not Authorised
2.2.3	<i>Biological medicinal products</i>	
	2.2.3.1 Blood products	Not Authorised
	2.2.3.2 Immunological product	Not 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	Not Authorised
	2.2.3.6 Human or animal extracted products	Not Authorised
	2.2.3.7 Other biological medicinal products	Not Authorised
	<i>Not Authorised</i>	
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	Not 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
	<i>Not Authorised</i>	





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





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

The site is not approved for manufacturing activities in the EU other than cells used for QC testing only.

1. Building(s)/Area(s)

N/A

2. Room(s)

N/A

3. Line(s) Equipment(s)

N/A

4. QC testing

Site is approved for testing of biological products using the usual range of biotech assays. In particular, the site may perform Virus testing and mycoplasma tests. The site may also perform microbiological testing (not sterility testing)

5. Medicinal Product(s)/IMP(s)

Biological product testing was examined.

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

Des Makohon
GMP Inspector
Des.Makohon@mhra.gsi.gov.uk

Date: 01/09/2009

