Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 35210 Insp GMP 35210/935445-0001 [H]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : WUXI APPTEC INCORPORATED

Site address : WUXI APPTEC INCORPORATED, 4751 LEAGUE ISLAND BLVD, PHILADELPHIA, 19112, UNITED STATES
Other :
Is a contract laboratory that has been inspected in accordance with the Medicines Act as amended

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 Regulation B17 of the Human Medicines Regulations 2012 (as amended)

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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
			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 aslo perform microbiological testing (not sterility testing)	Biological product testing was examined.

01/09/2009	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential