

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 APPTec INCORPORATED
Site address 1265-B KENNESTONE CIRCLE
 MARIETTA
 30066
 UNITED STATES

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2) of Regulation (EC) 726/2004 transposed in the following national legislation: Regulation 3(a) of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations (SI 2005/2789) and Section 19(3) of the Medicines Act 1968 as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 01/06/2009, 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.





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

The site is approved for sterility, endotoxin and bioburden testing only.

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

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

John Clarke
GMP Inspector
John.Clarke@mhra.gsi.gov.uk

Date: 25/06/2009



Note: Pages 2-7 describe non-applicable operations and therefore are not included in the copy of this certificate (Note by WuXi AppTec-Atlanta).