



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Certificate of GMP Compliance of a Manufacturer

**Certificate Number:**

MI-2013-CE-08047-1

**Issued to:**

Wuxi Apptec Inc

**Manufacturing Site Address:**

2540 Executive Drive  
St Paul Minnesota 55120  
UNITED STATES OF AMERICA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer has been inspected following Part 3-3, section 33B of the *Therapeutic Goods Act 1989* in connection with manufacturers of Biologicals (items made from or containing human cells or human tissues) located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of, that was conducted on 05 to 06 December 2013, it is considered that the manufacturer complies with the Good Manufacturing Practice (GMP) requirements of the Australian Code of Good Manufacturing Practice for Human Blood and Tissues (2000).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

**EXPIRY DATE: 06 June 2016**

**ISSUE DATE: 10 December 2014**

Name and signature of an authorised person of the Competent Authority of Australia:

Signed:

  
.....  
Katherine Clark  
Office of Manufacturing Quality

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible.  
This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.  
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.



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### MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Testing Laboratory	Not applicable	Not Applicable	Not Applicable	Testing biological

The following conditions are applicable to these manufacturing operations:

The biological testing is restricted to the testing of human tissue products for osteoinduction.

Name and signature of an authorised person of the Competent Authority of Australia:

Signed:

.....  
Katherine Clark  
Office of Manufacturing Quality

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