



CERTIFICATE NUMBER: 2010-035

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**  
**Part 1**

Issued following an inspection in accordance with:  
 Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Ireland confirms the following:  
 The manufacturer: **BioClin Research Laboratories**  
 Site address: **Monksland, Athlone, Co. Westmeath, Ireland**

Other:  
 This contract laboratory has been inspected under the national inspection programme in connection with Laboratory Approval no. L027, as a site of QC testing in accordance with Art 40 of Directive 2001/83/EC transposed into the following national legislation: Medicinal Products (Control of Manufacture) Regulations 2007 and 2009

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2010-02-22, 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	
<b>1 MANUFACTURING OPERATIONS</b>	
<p>- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;</p> <p>- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;</p> <p>- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form.</p>	
<b>1.6</b>	<b>Quality control testing</b>
	1.6.3 Chemical/Physical

2010-03-29

Name and signature of the authorised person of the  
Competent Authority of Ireland

**CERTIFIED IRISH MEDICINES BOARD**

**Cormac Dalton**  
**Irish Medicines Board**

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