

# **GMP- Certificate Nr: NL/H 11/0084**

PUBLIC HEALTH SUPERVISORY SERVICE  
HEALTH CARE INSPECTORATE



## **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 Netherlands confirms the following:

The manufacturer     **Bactimm B.V.**  
Site address           **Middenkampweg 19**  
                              **6545 CH Nijmegen**  
                              **The Netherlands**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **4012 ALAB** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: The medicines Act, article 100.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **22 June 2011**, 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. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified with the issuing authority.

Issue Date: 31 October 2011  
Signature:

A large, stylized handwritten signature in blue ink, consisting of several overlapping loops and a long tail.

O. Jellema, Pharmacist  
Inspector, Health Care Inspectorate, The Netherlands  
+ 31 70 304 1624

**Part 2**

<input checked="" type="checkbox"/> Human Medicinal Products <input checked="" type="checkbox"/> Veterinary Medicinal Products <input checked="" type="checkbox"/> Human Investigational Medicinal Products
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**1 MANUFACTURING OPERATIONS**

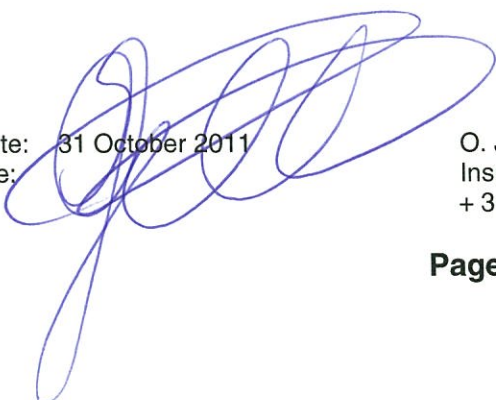
- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- 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.

1.6	Quality control testing	Yes	No
		<input checked="" type="checkbox"/>	<input type="checkbox"/>
	1.6.1 Microbiological: sterility	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	1.6.2 Microbiological: non-sterility	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	1.6.3 Chemical/Physical	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.6.4 Biological	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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

N.a.

Issue Date: 31 October 2011  
 Signature:



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