

**Inspectie voor de Gezondheidszorg - Geneesmiddelen en Medische  
Technologie**

CERTIFICATE NUMBER: *NL/H 11/0011*

**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 Netherlands confirms the following:

The manufacturer: *Lancaster Laboratories*

Site address: *2425 New Holland Pike, Lancaster, 17605, United States*

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 19(3) of Regulation 726/2004/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on *2011-01-20* , 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.

**Part 2**

Human Medicinal Products

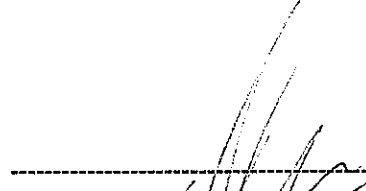
**1 Manufacturing Operations**

- 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 potential hazardous active ingredients this should be stated under the relevant produce type and dosage form;

<b>1.6</b>	<b>Quality control testing</b>
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

2011-01-27

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



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