

GMP- Certificate Nr: NL/H 11/0076

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:

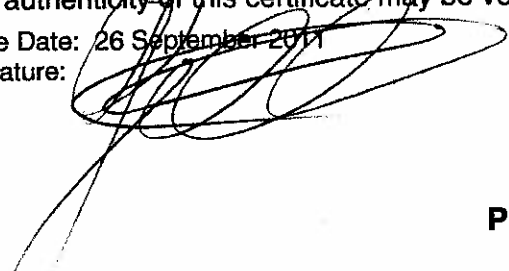
The manufacturer **Cambridge Major Laboratories Europe B.V.**

Site address **Vliesvenweg 1
6002 NM Weert
The Netherlands**

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) 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 **31 August 2011 and 1 September 2011**, it is considered that it complies with the principles of Good Manufacturing Practices for active substances referred to in Article 47 of Directive 2001/83/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: 26 September 2011
Signature: 

Name: A.J. Smalzenbroek, MSc. Pharm
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Inspector, Health Care Inspectorate, The Netherlands

Part 2

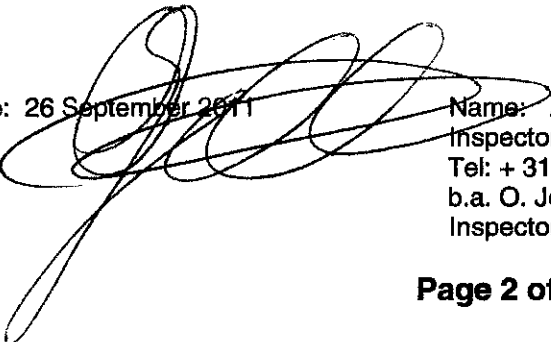
Manufacture of active substance. Names of substances subject to inspection:

Phenelzine Sulfate

Contract manufacture of active pharmaceutical ingredients used in clinical trials.

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

Active substances produced by chemical synthesis

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Signature: 

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