

GMP- Certificate Nr: NL/H 10/0103

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 **Farmalyse B.V.**
Site address **Pieter Liefstinckweg 2**
 1505 HX Zaandam
 The Netherlands

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **4731 F and 101037** 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 **12 May 2010**, 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.

Issue Date: 29 November 2010
Signature:

O. Jellema, Pharmacist
Inspector, Health Care Inspectorate, The Netherlands
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