

## **GMP- Certificate Nr: NL/H 11/0059**

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 **Laboratorium Ofichem B.V.**

Site address **Heembadweg 5  
9561 CZ Ter Apel  
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 30 June 2011 and 1 July 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: 11 July 2011

Signature:

A handwritten signature in blue ink, appearing to be 'A.J. Smallenbroek'.

Name: A.J. Smallenbroek, Pharmacist  
Inspector, Health Care Inspectorate, The Netherlands  
Tel: +31 (0) 70 304 1645

## **Part 2**

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

- Cisplatin
- Carboplatin
- Pamidronic acid
- Disodium pamidronate
- Dimethylfumarate
- Calcium-monoethylfumarate
- Magnesium-monoethylfumarate
- Zinc-monoethylfumarate
- Sulfadiazine sodium
- Sulfadimidine sodium
- Sulfathiazole sodium
- Sulfadimethoxine sodium
- Sulfamethoxypyridazine sodium
- Sulfachloropyridazine sodium
- Levamisole

Issue Date: 11 July 2011

Signature:



Name: A.J. Smallenbroek, Pharmacist  
Inspector, Health Care Inspectorate, The Netherlands  
Tel: +31 (0) 70 304 1645