

GMP- Certificate Nr: NL/H 11/0104

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 **Ansynth Service B.V.**

Site address **Jan Vermeerlaan 204
4703 LE Roosendaal
The Netherlands**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. EL 102275 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 4 October 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: 9 January 2012

Signature:

Ir. M. van Berlo

Inspector, Health Care Inspectorate, The Netherlands
+ 31 70 304 1605

Part 2

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 type="checkbox"/>	<input checked="" type="checkbox"/>
	1.6.2 Microbiological: non-sterility	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.6.3 Chemical/Physical	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	1.6.4 Biological	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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

Quality control testing of amino acids only.

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