Statens legemiddelverk
Norwegian Medicines Agency

TO WHOM IT MAY CONCERN

[redacted]

Your ref.:	Date:	Our ref.:	Office/Officer:
	27 November 2012		Seksjon for forvaltning/

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER[1] – PART I

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC as amended and Art. 15 of Directive 2001/20/EC the competent authority of Norway confirms the following:

Has been inspected under the national inspection program in connection with manufacturing authorisation no. 9092-3 in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC transposed in the Norwegian Act of 4 December 1992 on Medicinal Products etc.

and

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the Norwegian Act of 4 December 1992 on Medicinal Products etc.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 24 August 2012, it is considered that it complies the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[2] and the principles of GMP for active substances[2] 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.
The authenticity of this certificate may be verified with the issuing authority.

[1] The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC as amended, shall also be required for imports coming from third countries into a Member State.

[2] These requirements fulfill the GMP recommendations of WHO

Letters should be addressed to the Norwegian Medicines Agency. Please state our reference

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CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER – PART II

Human Medicinal Products
Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS - authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), quality control testing, 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.	
1.2	**Non-sterile products**
1.2	*1.2.1 Non-sterile products* 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.12 Suppositories 1.2.1.13 Tablets
	1.2.2 Batch certification only
1.4	**Other products or manufacturing activity** (any other relevant manufacturing activity/ product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation),herbal or homoeopathic products, bulk or total manufacturing, etc.)
	1.4.1 Manufacture of: 1.4.1.4 Other - Active Pharmaceutical Ingredients
1.6	**Quality Control testing**
	1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

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

Any restrictions or clarifying remarks related to the scope of this certificate: Only section 1.2.1.13 and 1.6 is applicable for Human Investigational Medicinal Products.

Yours sincerely
Norwegian Medicines Agency

(by authority)
Director of Department

NORWEGIAN MEDICINES AGENCY

Advisor