Sundhedsstyrelsen

Danish Health and Medicines Authority

Certificate No. DK H 00035713

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC as amended.

The competent authority of *Denmark* confirms the following:

The manufacturer Allergica a.m.b.a.

Site address Hagemannsvej 11
8600
Silkeborg
Denmark

has been inspected under the national inspection programme in connection with manufacturing authorisation no. 24471 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: *(Consolidated) Medicinal Products Act, 2005, as amended.*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2013/05/16, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC2.

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.

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Part 2

Human Medicinal Products

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 are specified under the relevant items.
- If the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients this is stated under the relevant product type and dosage form.

1.2	**Non-sterile products**
	1.2.1 Non-sterile products *Non-sterile products* 1.2.1.6 Liquids for internal use *Liquids for internal use* 1.2.1.8 Other solid dosage forms *Other solid dosage forms* *Powder for oral use*
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of: *Manufacture of:* 1.4.1.2 Homoeopathic products *Homoeopathic products*

Manufacture of active substance. Names of substances subject to inspection:
None

Any restrictions or clarifying remarks related to the scope of this certificate:
Not applicable

Date: 2013/07/09

Name and signature of the authorised person
of the competent authority of Denmark:

.....
Kasra Ghasemi

Danish Health and Medicines Authority

E-mail: dkma@dkma.dk