Danish Medicines Agency

CERTIFICATE NUMBER: ***DK API-H 10001080***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

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: ***Niels Clauson-Kaas A/S***
Site address: ***Rugmarken 28, Farum, 3520, Denmark***
OMS Organisation Id. / OMS Location Id.: ***ORG-100020586*** / ***LOC-100029343***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-11-28***, it is considered that it complies with::

- The principles of GMP for active substances [3] 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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

Clarifying remarks (for public users)

The manufacturer (Manufacturer of active substance) produces a range of syntetic non-sterile APIs for pre-clinical studies and clinical trial I-III. Starting materials, excipients, advanced stage intermediates and APIs. Process development, Production, Analytical test Method Qualification and Validation, Quality Control, Packaging, Release and Stability studies.

2024-12-18

Name and signature of the authorised person of the Competent Authority of Denmark

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Confidential
Danish Medicines Agency
Tel:***Confidential***
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