

Danish Medicines Agency

CERTIFICATE NUMBER: **DK IMP 1000523**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER ^{1,2}

Part 1

Issued following an inspection in accordance with :

Art. 63 of Regulation (EU) 536/2014

The competent authority of Denmark confirms the following:

The manufacturer: ***SPECIFIC PHARMA A/S***

Site address: ***Borgmester Christiansens Gade 40, Copenhagen Sv, 2450, Denmark***

OMS Location: ***LOC-100023722***

Has been inspected under the national inspection programme in accordance with Art. 61 of Regulation (EU) No 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2022-04-21**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC ³

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. 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.

¹The certificate referred to in paragraph Art. 15 of Directive 2001/20/EC, shall also be required for imports coming from third countries into a Member State.

²Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS

1.4 Other products or manufacturing activity

1.4.3 *Other: Storage of retention samples on behalf of other manufactures. (en)*

1.5 Packaging

1.5.2 *Secondary packaging*

2 IMPORTATION OF MEDICINAL PRODUCTS

2.3 Other importation activities

2.3.1 *Site of physical importation*

2.3.4 *Other: High-dose vitamins and minerals. Medicinal products delivered in accordance with compassionate use permit for clinical trials in DK only. (en)*

2022-07-22

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



Jan Hassel-Pflugh
Danish Medicines Agency

Tel:

Fax: