*National Agency For The Safety Of Medicine And Health Products*

CERTIFICATE NUMBER : ***2021/HPF/FR/075***

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

## Part 1

Issued following an inspection in accordance with :
Art. 15 of Directive 2001/20/EC

The competent authority of France confirms the following:
The manufacturer :***CAPSUGEL PLOËRMEL***
Site address :***ZI DE CAMAGNON, PLOËRMEL, 56800, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***2021_082_1_2*** in accordance with Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-11-26*** , 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.

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

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

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

## Part 2

| Human Investigational Medicinal Products |
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| 1 MANUFACTURING OPERATIONS | |
|---|---|
| **1.1** | **Sterile products** |
| | *1.1.2 Terminally Sterilised (processing operations for the following dosage forms)*<br>1.1.2.2 Semi-solids<br>Special Requirements<br>7 Other: Highly potent products(en) |
| | *1.1.3 Batch certification* |
| **1.2** | **Non-sterile products** |
| | *1.2.1 Non-sterile products (processing operations for the following dosage forms)*<br>1.2.1.1 Capsules, hard shell<br>Special Requirements<br>7 Other: Highly potent products(en)<br>1.2.1.2 Capsules, soft shell<br>Special Requirements<br>7 Other: Hormones - Highly potent products(en)<br>1.2.1.8 Other solid dosage forms: coated, granules, granules for oral suspension(en) |
| | *1.2.2 Batch certification* |
| **1.5** | **Packaging** |
| | *1.5.1 Primary Packaging*<br>1.5.1.1 Capsules, hard shell<br>Special Requirements<br>7 Other: Highly potent products(en)<br>1.5.1.2 Capsules, soft shell<br>Special Requirements<br>7 Other: Hormones - Highly potent products(en)<br>1.5.1.8 Other solid dosage forms: coated granules, granules for oral suspension(en) |
| **1.6** | **Quality control testing** |
| | *1.6.3 Chemical/Physical* |

| 2 IMPORTATION OF MEDICINAL PRODUCTS | |
|---|---|
| **2.1** | **Quality control testing of imported medicinal products** |
| | *2.1.3 Chemical/Physical* |

| | |
|---|---|
| **2.2** | **Batch certification of imported medicinal products** |
| | *2.2.1 Sterile products*<br>2.2.1.1 Aseptically prepared<br>2.2.1.2 Terminally sterilised |
| | *2.2.2 Non-sterile products* |
| | *2.2.3 Biological medicinal products*<br>2.2.3.2 Immunological products<br>2.2.3.5 Biotechnology products |
| **2.3** | **Other importation activities** |
| | *2.3.1 Site of physical importation* |

Clarifying remarks (for public users)

***1.1.2.2: Production is limited to the manufacture of bulk product and excludes the terminal sterilization operation --- Signatory: Mrs Florence Descamps-Delesalle, head of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good manufacturing practice certificates.***

***2021-05-27***

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

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