French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: ***2019/HPF/FR/117***

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

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***M 19/083*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Art. L.5124-3 of Public Health Code

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-04-20*** , 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 Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.2 Semi-solids Special Requirements 7 Other: Highly potent products(en)
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell Special Requirements 7 Other: Highly potent products(en) 1.2.1.2 Capsules, soft shell Special Requirements 7 Other: Highly potent products(en)
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

1.1.2.2 Production is limited to the manufacture of bulk product and exclues the terminal sterilization operation. 1.6.2 Microbiological controls are limited to those carried out for area monitoring Signatory: Mr Said Ioughlissen, deputy head of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good manufacturing practice certificates.

Chambre de commerce et d'industrie de région Paris Ile-de-France
16.04.19 171536

2019-04-11

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

CAPSUGEL Ploërmel
Claire GOUVERITH
Pharmacien Responsable
Z.I. de Camagnon - 56803 Ploërmel Cedex
Tél. 02 97 72 10 00 - Fax 02 97 72 15 00

Confidential
French National Agency for Medicines and Health Products Safety
Tel: *Confidential*
Fax: *Confidential*

Chambre de commerce et d'industrie de région Paris Ile-de-France
Vu exclusivement pour certification matérielle de la signature de
GOUVERITH
(seen exclusively to certify the above signature)
Pour le président, Achraf BOUKDIR

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. *République française* CHILI

Le présent acte public

2. a été signé par A. BOUKOIR

3. agissant en qualité de **Attaché**

4. est revêtu du sceau/timbre de **Chambre de Commerce et d'Industrie de Paris**

Attesté

5. à Paris

6. le 03 JUIN 2019

7. *par le Procureur général près la Cour d'appel de Paris*

8. sous n° 9176

9. Sceau :

10. Signature :

Michel LERNOUT
PREMIER AVOCAT GÉNÉRAL

"L'Apostille confirme seulement l'authenticité de la signature, du sceau ou timbre sur le document. Elle ne signifie pas que le contenu du document est correct ou que la République française approuve son contenu"