Chili
048032

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: ***2019/HPF/FR/180***

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: ***UNITHER INDUSTRIES***
Site address: ***Zone Industrielle Le Malcourlet, GANNAT, 03800, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***M 19/118*** 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 ***2019-02-21*** , 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.

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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	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.8 Other solid dosage forms: powder, granules(en) 1.2.1.12 Suppositories Special Requirements 7 Other: hormones(en) 1.2.1.13 Tablets
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.8 Other solid dosage forms: powder, granules(en) 1.5.1.12 Suppositories Special Requirements 7 Other: hormones(en) 1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

Clarifying remarks (for public users)

Signatory: Mr Said Ioughlissen, deputy head of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue hard copies of good practice certificates.

2019-06-25

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

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

Y. CHANE-YENE

BAILLY CAURO
NOTAIRES ASSOCIÉS D'UNE SCP
8 rue Auber - Paris - 9e

Je soussigné Me Antoine BAILLY
I the undersigned
notaire à Paris, certifie matériellement la
notaire in Paris, certify the
signature de/of M. Yves CHANE-YENE.
apposée sur le présent document.
apposed on the present document.
Cette certification ne comporte aucune vérification
This certification doesn't contain any verification
de l'exactitude des faits et actes mentionnés
of the accuracy of facts mentionned
dans le présent document.
in the present document.

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. *République française* CHTU

Le présent acte public

2. a été signé par... **Me BAILLY**

3. agissant en qualité de... **Notaire**

4. est revêtu du sceau/timbre de... **Son étude**

Attesté

5. à Paris

6. le... 11 JUIL. 2019

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

8. sous n° 22139

9. Sceau :

10. Signature :

Michel LERNOUT
PREMIER AVOCAT GÉNÉRAL

COUR D'APPEL DE PARIS

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"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"