French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: ***HPF/FR/284/2017***

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: ***LABORATOIRE UNITHER - AMIENS***
Site address: ***Espace Industriel Nord, 151 rue André Durouchez CS 28028, AMIENS, 80084 CEDEX 2, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***MM 16/194*** 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 ***2017-07-07*** , 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.*

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.3 Semi-solids 1.1.1.4 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.5 Liquids for external use
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

Signatory: Mrs Mélanie Cachet, head of pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good practice certificates.

EudraGMDP

2017-11-20

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***

Marc FERON
Deputy Pharmacist
November 29th, 2018

LABORATOIRE UNITHER
Marc FERON
Responsable Qualité / Quality Manager
Pharmacien délégué Deputy Pharmacist / Deputy QP
N° d'ordre des Pharmaciens Order of the Pharmacists Nr : 986528

N° 667
Vu exclusivement pour certification matérielle de la signature de M. Feron
Seen exclusively to certify the above signature
AMIENS, le 29 NOV 2018
Pour la Présidente

CHAMBRE DE COMMERCE ET D'INDUSTRIE CCI AMIENS-PICARDIE

Delphine LENGLET
Responsable formalités internationales

EudraGMP

APOSTILLE
(Convention de la Haye du 5 octobre 1961)

1. - République française
Le présent acte public

2. - a été signé par Delphine LENGLET

3. - agissant en qualité de RESPONSABLE FORMALITES ENTREPRISES

4. - est revêtu du sceau de la **CHAMBRE DE COMMERCE ET D INDUSTRIE AMIENS PICARDIE**

Attesté

5. - à Amiens **6.** - Le 04 Décembre 2018

7. - Par le Procureur Général près la Cour d'Appel d'Amiens

8. - sous le numéro 1982/2018

Eric BOUSSUGE
Avocat Général

9. - **Sceau**

10. - **signature**

PROCUREUR GÉNÉRAL PRÈS LA COUR D'APPEL D'AMIENS

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