National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER: ***23MPP072HVFR01***

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

Part 1

Issued following an inspection in accordance with
Art. 94(1) of Regulation (EU) 2019/6 as amended
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of France confirms the following:
The manufacturer: ***Oleon***
Site address: ***Rue Les Rives De L Oise, Venette, 60280, France, GPS: 49.427503, 2.820388***
OMS Organisation Id. / OMS Location Id.: ***ORG-100025317*** / ***LOC-100054308***

Is an active substance manufacturer that has been inspected in accordance with Art. 123(6) of Regulation (EU) 2019/6 and Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-12-13***, it is considered that it complies with:

- The principles of GMP for active substances [3] referred to in and Article 47 of Directive 2001/83/EC.

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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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 Art. 80(5) of Directive 2001/82/EC and Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

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

Part 2

Manufacture of active substance. Names of substances subject to inspection:
GLYCEROL(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance:GLYCEROL	
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.6 Purification of extracted substance Plant
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Clarifying remarks (for public users)

Signatory : Mrs Aurélie DEMARCQ, head of starting materials inspection department --- The ANSM does not issue hard copies of good practices certificates

2024-03-10

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

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