

**Federal Agency for Medicines and Health Products**

CERTIFICATE NUMBER: **BE/GMP/2018/132**

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER** <sup>1, 2</sup>

**Part 1**

Issued following an inspection in accordance with :  
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Belgium confirms the following:

The manufacturer: **Alcon-Couvreur NV**

Site address: **Rijksweg 14, Puurs, 2870, Belgium**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **176 H** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:

**Article 12 bis, § 1 of the Law of 25th March 1964 related to the Medicinal Products**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2018-11-09**, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC <sup>3</sup>

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.

<sup>1</sup> 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.

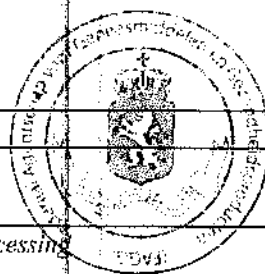
<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup> These requirements fulfil the GMP recommendations of WHO.

Chilo 162283

## Part 2

Human Medicinal Products	
<b>1 MANUFACTURING OPERATIONS</b>	
<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.3 Semi-solids 1.1.1.4 Small volume liquids Special Requirements 7 Other: prostaglandin(en)
	<i>1.1.3 Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products (list of product types)</b>
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.5 Biotechnology products
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.2 Secondary packing</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>
<b>2 IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	<i>2.1.1 Microbiological: sterility</i> <i>2.1.2 Microbiological: non-sterility</i> <i>2.1.3 Chemical/Physical</i> <i>2.1.4 Biological</i>
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
<b>2.3</b>	<b>Other importation activities</b>
	<i>2.3.1 Site of physical importation</i>
	<i>2.3.2 Importation of intermediate which undergoes further processing</i>





# The State of Texas

## Secretary of State

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This Apostille only certifies the signature, the capacity of the signer and the seal or stamp it bears. It does not certify the content of the document for which it was issued.

Certificate Validation available at [www.sos.state.tx.us](http://www.sos.state.tx.us)

### APOSTILLE

(Convention de La Haye du 5 Octobre 1961)

- |                                |  |
|--------------------------------|--|
| 1. Country                     | United States of America   |
| This public document           |  |
| 2. has been signed by          | CAROLE YOUNBI YAMDJEU  |
| 3. acting in the capacity of   | Notary Public, State of Texas  |
| 4. and bears the seal/stamp of | CAROLE YOUNBI YAMDJEU,<br>Notary Public, State of Texas,<br>Commission Expires: 05-21-22 |

### CERTIFIED

- |                                       |                     |
|---------------------------------------|---------------------|
| 5. at Austin, Texas                   | 6. on April 3, 2019 |
| 7. by the Secretary of State of Texas |                     |
| 8. Certificate No. 11704627           |                     |
| 9. Seal                               | 10. Signature:      |



A handwritten signature in black ink, appearing to read "David Whitley", written over a horizontal line.

David Whitley  
Secretary of State

GF/rm

Clarifying remarks (for public users)

2019-02-12



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

*[Signature]*  
DO Inspection  
part of European Industry

Mr. Xavier De Cuyper  
Federal Agency for Medicines and Health Products  
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State of Texas  
County of Tarrant

On this 29<sup>th</sup> day of March, 2019  
I certify that the preceding document, and the duplicate  
retained by me as a notarial record, are true, exact, complete  
and unaltered photocopies made by me of

Certificate BE/GMP/2018/132

presented to me by the document's custodian, Alcon  
Laboratories, and that, to the best of my knowledge,  
the photocopied document is neither a public record nor a  
publicly recordable document, certified copies of which  
are available from an official source other than a notary.

Carole Youmbi

