Nelson Labs.
A Sotera Health company

Leuven, 09 September 2020

Clarification on active certification of GMP compliance for Nelson Labs NV

To whom it may concern,

The last Good Manufacturing Practice (GMP) audit of the Federal Agency for Medicines and Health Products (FAMHP) took place on October 13th of 2017 and the resulting GMP certificates are valid for three (3) years. On June 6th of 2020 these certificates were extended with one (1) year.

As of September 29th of 2019, the FAMHP will no longer provide paper versions of certificates for GMP. As a result, the GMP certificates detailing the extension are not signed by an authorized person of the Competent Authority of Belgium (FAMPH). All GMP certificates can be queried in the EudraGMDP database (http://eudragmdp.ema.europa.eu). Only the Competent Authorities can upload certificates so that the information is guaranteed to be authentic and valid.

Sincerely yours,

Bart Boerjan
Quality Assurance Manager

afmps fagg
agence fédérale des médicaments et des produits de santé
federaal agentschap voor geneesmiddelen en gezondheidsproducten

EUROSTATION II
Place Victor Horta plein 40/40
1060 BRUSSELS (BELGIUM)
http://www.fagg-afmps.be

Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2017/115***

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

Part 1

Issued following an inspection in accordance with :
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Belgium confirms the following:
The manufacturer: ***Nelson Labs NV***
Site address: ***Romeinse straat 12, Leuven, 3001, Belgium***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***1844 V*** in accordance with Art. 44 of Directive 2001/82/EC transposed in the following national legislation:
Article 12 bis, § 1 from 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 ***2017-10-13*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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.

[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

Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
	2.1.4 Biological

2018-05-23

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

Philippe DE BUCK
Head of Division Authorisations
DG inspection - FAMHP

Mr. Xavier De Cuyper
Federal Agency for Medicines and Health Products
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Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten (FAGG)

Federal Agency for Medicines and Health Products

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	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
	2.1.4 Biological

Clarifying remarks (for public users)

The duration of validity of this GMP-certificate has been extended with 1 year.

2020-06-23

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

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Site address: ***Romeinse straat 12, Leuven, 3001, Belgium***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***1844 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

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- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
	2.1.4 Biological

2018-05-23

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Clarifying remarks (for public users)

The duration of validity of this GMP-certificate has been extended with 1 year.

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CERTIFICATE NUMBER: ***BE/GMP/2017/116***

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

Part 1

Issued following an inspection in accordance with :
Art. 15 of Directive 2001/20/EC

The competent authority of Belgium confirms the following:
The manufacturer: ***Nelson Labs NV***
Site address: ***Romeinse straat 12, Leuven, 3001, Belgium***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***1844 IMP*** in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation:
Article 24 from the Law of 7th May 2004 related to the experiments on the humans

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Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
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	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
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	2.1.3 Chemical/Physical
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Clarifying remarks (for public users)

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